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SYMPOSIUM ON FINANCING AND REGULATING HEALTH CARE SERVICES: HARD CHOICES AND ETHICAL DILEMMAS

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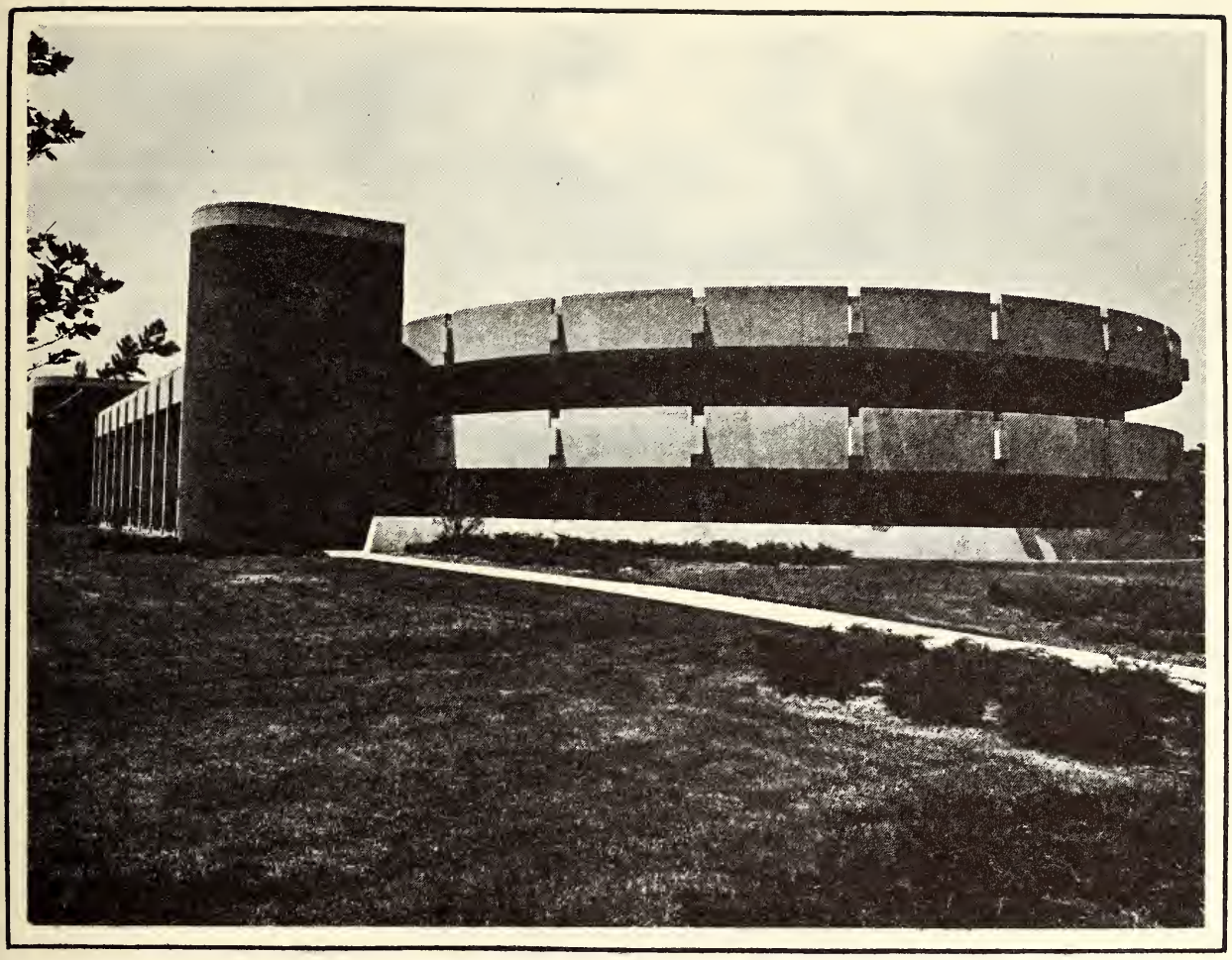

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Indiana Law Review

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Foreword

This Symposium marks the inauguration of the Program for Law, Medicine and the Health Care Industry at the Indiana University School of Law — Indianapolis. The primary mission of the program is to conduct scholarly research on health law issues of concern to the state of Indiana and to the nation. The Program has undertaken research on a variety of legal issues affecting the health care industry ranging from reform of the administrative appeals procedures for the Medicare program and medical malpractice to the thorny bioethical issues emerging in the treatment of individuals with AIDS. The program is also dedicated to improving teaching and enhancing the law school curriculum in the field of health law. Finally, the program is committed to serving as an information and educational resource for the health care community.

In this Symposium, entitled *Financing and Regulating Health Care Services: Hard Choices and Ethical Dilemmas*, the Program joins the *Indiana Law Review* in drawing together several disparate voices in a discussion of the implications of adjusting the financing and regulation of health care services to accommodate diminishing resources for and increasing constraints on the health care system. The Symposium opens with an article by Randall R. Bovbjerg of The Urban Institute and William G. Kopit of Epstein Becker Borsody & Green, Washington, D.C. entitled *Coverage and Care for the Medically Indigent: Public and Private Options*. In this comprehensive examination of the problem of "uncompensated care," the authors evaluate alternative ways of organizing and financing coverage or care for the medically indigent. The authors bring to this topic significant expertise in health policy. Mr. Bovbjerg has conducted extensive research on insurance and health policy issues and served as a practicing insurance regulator and health specialist at the Massachusetts Insurance Department. In addition to representing a number of hospitals and hospital associations, Mr. Kopit served on the Task Force on Indigent Care of the District of Columbia Hospital Association and chaired its subcommittee on financing indigent care.

In the second article, Carl T. Schramm, former chairman of the Maryland Health Care Cost Review Authority and a leading scholar of hospital rate-setting issues for the last decade, examines the political process underlying state efforts to reform hospital financing mechanisms. In

State Hospital Cost Containment: An Analysis of Legislative Initiatives, Professor Schramm identifies the interested parties and describes the position each party is likely to take, the dynamics of various legislative tactics, and the likely outcomes of state rate-setting initiatives.

Two articles by Clark C. Havighurst of the Duke University School of Law follow. In the first, *Liver Transplantation in Massachusetts: Public Policymaking as Morality Play*, Professor Havighurst and Nancy M.P. King present the story of Jamie Fiske as a case study of how a centrally-controlled health care system faces difficult choices concerning health care and health care technology. In the second, *The Lithotripsy Game in North Carolina: A New Technology Under Regulation and Deregulation*, Professor Havighurst and Robert S. McDonough examine how one state handled the distribution of a costly and highly sophisticated new technology in two contrary contexts — regulation and deregulation.

Even though the federal government no longer mandates health planning and certificate of need, many states have retained these strategies to control distribution of health care facilities and services. In *Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*, James B. Simpson, the Director of the Legal Resources Program at the Western Center for Health Planning, recounts the changes that have evolved in the scope of coverage of state certificate of need programs from their origins to the present.

In *Reform Revisited: A Review of the Indiana Medical Malpractice Act Ten Years Later*, James D. Kemper, Myra C. Selby, and Bonnie K. Simmons of Ice Miller Donadio and Ryan, Indianapolis, describe one state's attempt to address the medical malpractice "crisis" of the 1970's. These authors, leading health law practitioners in the state of Indiana, consider in turn the original purpose of the Indiana Act, the impact of recent amendments, the functioning of the medical review panel, constitutional challenges to the Act and the impact of federal cost containment measures on state malpractice law.

These articles, with their focus on state law issues, emphasize the critical development of health policy in the 1980's: the flow of financial and programmatic responsibility for government health programs to the states. This development has resulted in increased state interest in addressing the pressing health policy issues of today, i.e., paying for care for the medically indigent, controlling hospital costs, mitigating the threat of medical malpractice to access to and cost of medical care, and the ever present pressure to impose rationality on the distribution of health care resources through planning and regulation.

The final three articles address health policy issues arising at the federal level. Throughout the 1980's, the federal government has retained the dominant role in the public financing of health care services through the Medicare and Medicaid programs and, since 1980, has adopted a radically different system for paying for hospital services under the Medicare pro-

gram — the prospective payment system with prices based on patient diagnosis. In *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, Eleanor D. Kinney, Director of the Program for Law, Medicine and the Health Care Industry, analyzes the administrative model by which the federal government and also hospitals and physicians make decisions about the allocation of hospital services to Medicare beneficiaries under the Medicare prospective payment system. In *Bowen v. American Hospital Association: Federal Regulation Is Powerless to Save Baby Doe*, Dennis Cantrell of Bingham Summers Welsh & Spilman, Indianapolis, explores the Reagan Administration's effort, born of a profound commitment to the preservation of fetal life, to regulate treatment of severely handicapped newborns through federal civil rights laws, and the Supreme Court's response. The Symposium closes with a student note on how the predominant federal economic policy of promoting competition in the marketplace through the antitrust laws plays out with respect to one aspect of the health care system. In *Denying Hospital Privileges to Non-Physicians: Does Quality of Care Justify a Potential Restraint of Trade?*, the author proposes heightened judicial scrutiny of a hospital's claim that quality of care concerns justify its denial of staff privileges to a group of competitors.

Our foreword to this Symposium would be incomplete without acknowledging the numerous people who assisted in this endeavor. Specifically, we would like to thank the editorial board and staff of the *Indiana Law Review*, particularly Gayle Reindl and Debra McVicker. We would also like to recognize the support and encouragement of Gerald L. Bepko, former Dean of the law school and now Vice President of Indiana University-Purdue University at Indianapolis. Finally, we would like to thank Mabel K. Hart of the Program staff and law students Kimberlie L. Forgey, Barbara A. Knotts, Marilyn Wilder, and Michael D. Wright for their invaluable assistance in the production of this Symposium.

Eleanor D. Kinney

Barbara McCarthy Green

Coverage and Care for the Medically Indigent: Public and Private Options

Randall R. Bovbjerg*
William G. Kopit**

I. Introduction

As of March 1984, about 35 million people had no health insurance coverage, public or private, although some of them were only temporarily uncovered. Up to 40-odd million more, often called the "underinsured," had incomplete coverage.[1] These people, with little or no insurance, need periodic medical attention as much as or more than the well insured, but face far more trouble getting it.[2] Often, they have been forced to rely on the charity of providers, particularly hospitals.

From a hospital's viewpoint, the issue is how much "uncompensated care" to give. As every newspaper reader or "Sixty Minutes" viewer knows, hospitals in today's more competitive environment have more limited ability to care for the needy with public funds or from margins earned caring for the better-off.[3] From the patient's perspective, the problem is access to care. One hears of patients being shuttled from hospital to hospital in search of care, even when the need seems urgent,[4]

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* *

The authors gratefully acknowledge the assistance of Joyce Cowan, Associate with the firm of Epstein Becker Borsody & Green, P.C., in preparing this Article.

* *

[1]On the numbers of uninsured and underinsured, see *infra* text accompanying notes 11-29.

[2]*See infra* text accompanying notes 27-29.

[3]According to data from the American Hospital Association, for the year ending June 1986, hospitals' net patient margin was only 0.8%; total net margin (including non-patient revenues) was 5.4%, down from 2.0% and 6.3% the previous year. Hosp. Research & Educ. Trust, *Selected Hospital Performance Indicators: June 1985 & 1986,* Econ. Trends, Fall 1986, at 5.

[4]*See, e.g.*, Cahan & Pave, *When the Patient Can't Pay the Medical Bill*, Bus. Wk., Feb. 18, 1985, at 59; Taylor, *Ailing, Uninsured and Turned Away*, Washington Post, June 30, 1985, at A1, col. 3.

and of hospitals "dumping" impecunious patients on the nearest public hospital legally obligated to take them.[5] The problems that poor patients have in receiving more routine care from physicians, hospital outpatient departments, or other providers are far less dramatic or well documented.

The intertwined problems of the uninsured population and of uncompensated care have grown rapidly in the recent past and are likely to continue to grow in the near future. Private insurance, public programs, and hospital margins are all in a "cutback" era, and unfortunately, the uninsured are on the cutting edge.[6]

Under our legal system, states and localities bear the ultimate responsibility for fashioning whatever responses are made. Indeed, the uninsured/uncompensated care problem was high on the agenda of most state legislatures during the 1986 sessions and will probably remain so for 1987.[7] Billions of dollars in new assistance seem needed. The current federal administration is unlikely to offer new assistance for these efforts.[8] Thus, it seems likely that the usual American genius for weaving together various strands of partial solutions through varied mechanisms will have to come into play. This Article suggests what such mechanisms may be.

II. The Nature and Extent of Problems

A. The Medically Indigent and the Uninsured

The problem of providing health care for those who cannot or do not provide for themselves can be seen from a number of perspectives. In fact, there is no consensus on what "the" problem is. Localities around the country differ tremendously in their populations' medical needs and in their patterns of medical financing and delivery, and there is probably even more diversity in practical and philosophical approaches to proposed solutions in each area. Some people are concerned only about providing emergency care for the very poor and uninsured; others worry that even many insured people are not well covered and hence cannot pay, in full, providers who treat them.

Nevertheless, it seems clear that insufficient financing adversely affects access to care and, thus, the health of the medically indigent. By

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[5]*See, e.g.*, Schiff, Ansell, Schlosser, Idris, Morrison & Whitman, *Transfers to a Public Hospital*, 314 New Eng. J. Med. 552 (1986); Wrenn, *No Insurance, No Admission*, 312 New Eng. J. Med. 373 (1985); *The 'Dumping' Problem: No Insurance, No Admission* (letters) 312 New Eng. J. Med. 1522 (1985); Knox, *Some Local Hospitals 'Dump' The Uninsured*, Boston Globe, Feb. 6, 1984, at 31, col. 2.

[6]*See infra* text accompanying notes 46-64.

[7]*See, e.g.*, Intergovernmental Health Policy Project, George Washington Univ., Major Changes in State Medicaid and Indigent Care Programs (July 1986).

[8]*See infra* note 63.

"medically indigent," this Article means the class of people who cannot afford necessary medical care from their own resources or from health insurance coverage, if any.[9] It should be noted that the Article follows general usage by recognizing that even middle class people can become "medically" indigent when their net medical bills, after insurance, are very high relative to their income and assets. Of course, the likelihood of medical indigency is far less for such people than it is for those who begin with low incomes and little or no insurance coverage.

B. The Uninsured: Number and Characteristics

People without public or private health insurance are the core of the medical indigency problem.[10] People who have coverage, but coverage that does not fully protect against catastrophic losses—and hence against medical indigency—are a lesser problem.[11]

How many people are uninsured and face problems of medical access? Who are they and why do they lack resources? How much care do they get now? What is the extent of the financial shortfall? All of these pertinent questions can be answered only imperfectly from available evidence.

To understand who lacks coverage, one must appreciate how most

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[9]None of the three elements—necessary care, poverty, and lack of (adequate) insurance—readily allows of a clear-cut, operational definition. Opinions vary greatly on how much medical care is truly needed, on how poor one must be to be truly needy, and on what constitutes inadequacy in insurance. Moreover, deciding on medical indigency in advance of a known level of medical need (or spending) is even more difficult.

[10]"Insurance" as used here means any financing method available to a patient other than out-of-pocket payment or charity. Public coverage includes Medicare, Medicaid, and other medical assistance plans. Private coverage need not be "insurance" under the state insurance code. It may be conventional coverage from a commercial life and health insurance company, such as Prudential, or from a not-for-profit Blue Cross/Blue Shield plan; or it may be one of many alternative styles of coverage from a health maintenance organization (HMO), a preferred provider organization (PPO), or some other financing and delivery entity. Finally, it may resemble any of the above but be managed on a self-insured basis by an employment group that "insures" its own risk rather than placing it with a separate insurer.

[11]Such people generally have coverage for routine hospital stays and some physician and other services as well, but not for very large medical expenses. At some point, their uncovered bills become sizable compared with their income (especially if they cannot work), and they become medically indigent. The best estimate of the extent of such problems comes from 1977 national survey data indicating that 13% of the population under 65 was uninsured. Depending on the definitions applied, an additional 10 to 24% of the under-65 population is *under*insured. The smaller figure consists of those who have at least a 5% expectation of out-of-pocket expenses exceeding 10% of annual family income; the larger figure includes all those whose insurance does not limit out-of-pocket hospital expenses. Farley, *Who Are the Underinsured?*, 63 MILBANK MEM. FUND Q. 476 (1985); *see also* M. SULVETTA & K. SWARTZ, THE UNINSURED AND UNCOMPENSATED CARE 3, 19 (1986) (Tables 1 and 4).

Americans are covered. After World War II, private health insurance grew by leaps and bounds. Provided largely as a fringe benefit of employment, private coverage was greatly encouraged by its exclusion from income taxation and its inclusion as a subject of collective bargaining.[12] In 1965, public coverage took a quantum leap with the congressional enactment of Medicare, largely for the aged, and Medicaid, for the "deserving" poor, as defined by participating states.[13] Coverage continued to expand through the 1970's, not only in terms of the number of people covered but also in the breadth and depth of the benefits provided;[14] as a result, the number of uninsured people declined.[15]

In contrast, the early 1980's saw a rise in the number of people without coverage,[16] for reasons considered below. As of early 1984, about 35 million people under age sixty-five, or about seventeen percent of them, reported that they lacked health coverage at the time surveyed. Most of them were probably uninsured for the full year, some for only part of the year.[17]

Table 1 shows the growth in the uninsured population between 1977 and 1984.

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[12]In 1945, only 32 million people were privately covered for hospital inpatient care; by 1965, 139 million were. HEALTH INS. ASS'N. OF AMERICA, SOURCE BOOK OF HEALTH INS. DATA, 1986 UPDATE, Table 1.1, at 3. The average marginal "tax subsidy" for U.S. workers has been estimated to exceed 35% of premiums, C. PHELPS, TAXING HEALTH INSURANCE: HOW MUCH IS ENOUGH? (The Rand Corporation, Report P-6915, 1983), or about 10% of total private health insurance spending, CONGRESSIONAL BUDGET OFFICE, CONTAINING MEDICAL CARE COSTS THROUGH MARKET FORCES (May 1982). *See generally* Pauly, *Taxation, Health Insurance and Market Failure*, 24 J. ECON. LIT. 629 (1986).

[13]Social Security Act, tit. XVIII & XIX, 42 U.S.C §§ 1395, 1396 *et. seq.* (1982 & Supp. 1985).

[14]*See* HEALTH INS. ASS'N OF AMERICA, *supra* note 12.

[15]K. SWARTZ, WHO HAS BEEN WITHOUT HEALTH INSURANCE? CHANGES BETWEEN 1963 AND 1979 (Urban Institute, 1984).

[16]M. SULVETTA & K. SWARTZ, *supra* note 11, at 1, 3; *see also* HEALTH INS. ASS'N. OF AMERICA, *supra* note 12.

[17]M. SULVETTA & K. SWARTZ, *supra* note 11, at 3; *see also* K. SWARTZ, INTERPRETING THE ESTIMATES FROM FOUR NATIONAL SURVEYS OF THE NUMBER OF PEOPLE WITHOUT HEALTH INSURANCE: A PROJECT SUMMARY REPORT (Urban Institute, 1985). Surveys done in 1977 and 1980 compared those without coverage for the full year with those uncovered only part of the year. About three-quarters of those uninsured at a single point in time were uninsured all year; about 9% of 13%, for the 1977 survey. An additional 4% were uninsured part of the year. *See* M. SULVETTA & K. SWARTZ, *supra* note 11, at 3; Friedman, *Health Insurance and Cross-Subsidization*, HOSPITALS, Oct. 16, 1985, at 126. (interview with Jack Hadley and Katherine Swartz). Most estimates of the uninsured exclude people aged 65 and older because virtually all of them are now covered by Medicare, after the expansions of recent years to include federal workers and others.

TABLE 1
INCREASES IN THE UNINSURED OVER TIME
(SELECTED SURVEY ESTIMATES, UNDER AGE 65)

Year	Millions of Uninsured	Percentage of Population
1977	26.2	13.8%
1978	26.0	13.7
1980	28.6	14.6
1982	30.7	15.2
1983	32.7	16.1
1984	35.1	17.1

(adapted from M. SULVETTA & K. SWARTZ, *supra* note 11, Table 1).

Why have the numbers of uninsured people climbed? One reason is Medicaid cutbacks in eligibility, encouraged by recession-induced shortfalls in expected state revenues and required or encouraged by federal welfare and Medicaid changes in 1981.[18] Medicaid now covers only about forty percent of people below the poverty line.[19]

The recession of the early 1980's also put many people at least temporarily out of work and hence out of private health coverage as well.[20] Unemployment was especially high in heavy industry, hit by both recession and intensifying foreign competition. Jobs lost in this sector, traditionally the best insured area of the economy, often were not regained, and replacement jobs in service and other industries were far less likely to offer employer-paid health insurance.[21]

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[18]*See generally* R. BOVBJERG & J. HOLAHAN, MEDICAID IN THE REAGAN ERA: FEDERAL POLICY AND STATE CHOICES (1982); J. HOLAHAN & J. COHEN, MEDICAID: THE TRADE-OFF BETWEEN COST CONTAINMENT AND ACCESS TO CARE (1986). Medicare eligibility cutbacks, in contrast, have been minimal, largely achieved through administrative revisions in disability standards.

[19]J. HOLAHAN & J. COHEN, *supra* note 18. Medicaid covers about one-third of poor adults, one-half of poor children. *Id.* at 47. However, for various reasons, about one-third of Medicaid recipients have incomes *above* poverty levels. Conversely, the main reason so many poor people are not covered under Medicaid is the program's categorical nature; only certain categories of poor people can qualify. Notably, childless people and intact families are generally ineligible. *But see infra* notes 237, 239. Cutbacks among even eligible groups are also responsible. *See* J. HOLAHAN & J. COHEN, *supra* note 18.

[20]*See, e.g., Health Insurance for the Unemployed: Hearing Before the Subcomm. on Health of the Senate Comm. on Finance,* 98th Cong., 1st Sess. (1983); STAFF OF SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 98TH CONG., 1ST SESS., REPORT ON HEALTH BENEFITS: LOSS DUE TO UNEMPLOYMENT (Comm. Print 1983).

[21]*See, e.g.,* K. SWARTZ, THE CHANGING FACE OF THE UNINSURED (Urban Institute, May 1984); Friedman, *The Right Issue at the Wrong Time*, CHA INSIGHT, June 9, 1986, at 1; Friedman, *supra* note 17, at 126-27; *see also infra* note 45.

Moreover, even those who retained coverage at work in the 1980's often have found their coverage cut back. Cutbacks have taken the form of increased requirements for patient cost sharing, utilization review, and the like,[22] as well as decreased employer payment of insurance premiums, especially for dependents.[23]

What explains the lack of insurance among non-poor working adults? Obviously, their employers have not bought them insurance. Type of employment also matters, especially size of employment group, because insurance is much cheaper for large groups than for small ones or for individuals.[24] Beyond workplace characteristics comes individual willingness to pay for coverage; presumably nonbuyers either cannot afford coverage that is attractive to them or they do not appreciate its value.

One of the most discouraging findings of recent surveys is that households that contain at least one insured adult also contain many uninsured dependents. In fact, one third of all uncovered children—over 3 million children—came from such households.[25] Although direct causation is not established, presumably this lack of coverage reflects the worker's choice not to pay the additional amount necessary to obtain family coverage.[26]

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[22]*See, e.g.*, J. CALIFANO, AMERICA'S HEALTH CARE REVOLUTION: WHO LIVES? WHO DIES? WHO PAYS? (1986); P. FOX, W. GOLDBECK & J. SPIES, HEALTH CARE COST MANAGEMENT: PRIVATE SECTOR INITIATIVES (1984).

[23]*See, e.g.*, BUREAU OF LABOR STATISTICS, U.S. DEP'T OF LABOR, EMPLOYEE BENEFITS IN MEDIUM AND LARGE FIRMS, 1985 (1986). Having to pay for dependents out of pocket, with after-tax dollars, is a major disincentive to buying coverage, especially when that coverage features increasingly higher deductibles and coinsurance.

[24]On economies of larger-scale insurance, see, e.g., Bovbjerg, *Insuring the Uninsured Through Private Action: Ideas and Initiatives*, 23 INQUIRY 403 (1986). On large versus small employers, see, e.g., Moyer & Cahill, *HHS Survey Illustrates Difference in Large, Small Employers' Health Plans*, BUS. & HEALTH, Nov. 1984, at 50. Unfortunately for insurance coverage, some two-thirds of new jobs are created in small firms, mainly in the service industry. *See, e.g., In Praise of Pizza Parlours*, THE ECONOMIST, May 17, 1986, at 75. *See generally* Monheit, Hagen, Berk & Farley, *The Employed Uninsured and the Role of Public Policy*, 22 INQUIRY 348 (1985) (characteristics of employment that affect coverage).

[25]Friedman, *supra* note 17, at 128.

[26]Two other possible reasons for a decline in insurance coverage deserve brief mention. For various reasons, the proportion of households headed by women has risen, and these households are less likely than male-headed ones to have coverage, especially given Medicaid acts. *See id.* at 128. Moreover, to an unknown extent, more individuals have probably become "uninsurable" in the private market, especially outside of large employment group plans. Such people include those with chronic conditions needing care or adverse medical histories that put them at high risk of significant expense; they cannot get ordinary coverage without major exclusions. *See, e.g.*, Gottschalk, *People with Chronic Diseases Often Find Insurance Is Unaffordable—or Unavailable*, Wall St. J., Aug. 12, 1986, at 29, col. 3. This phenomenon is an unfortunate side effect of progress; medical treatment now saves many who formerly would have died (e.g., through better emergency care or cardiac resuscitation) but who now survive with an adverse health history. Additionally, medical

Who are the uninsured? They fit no simple stereotype. Common expectations are that the uninsured are exclusively poor, unemployed, young, and nonwhite. Persons with any of those characteristics are indeed at higher risk of being uninsured, as Table 2 shows.

TABLE 2
SOME CHARACTERISTICS THAT PUT PEOPLE AT HIGH RISK OF BEING UNINSURED (1984)

Group	Percentage Not Insured	Relative Risk
Entire under-65 Population	15.2%	1.00
Unemployed Adults	33.6%	2.21
Income Below Poverty Line	33.8%	2.22
Age 18-24	29.0%	1.91
Children Age 0-18 Below Poverty Line	34.1%	2.24
Blacks Age 18-64	25.0%	1.64
Never Married Males	30.6%	2.01
Married Female, Spouse Absent	36.0%	2.37
Children in Single-Parent Household	34.2%	2.25
Adults with No High School Diploma	25.5%	1.68

(computed from M. SULVETTA & K. SWARTZ, *supra* note 11, *passim*).

But, in fact, most of the uninsured have family incomes at least somewhat above the poverty line, are employed, are adults, and are white, as Table 3 shows. These people may thus seem less appealing for consideration as medical indigents; still, medical bills of a substantial size would clearly throw most of these people into the medically indigent category.

diagnosis has improved physicians' ability to predict future problems and hence insurance expenses; the most glaring example is screening for antibodies to the acquired immune deficiency syndrome (AIDS) virus.

TABLE 3
THE SHARE OF THE UNINSURED CONTRIBUTED BY GROUPS WITH CERTAIN CHARACTERISTICS (1984)

Characteristic	Percentages* of Under-65 Uninsured Who Are
Family Income (All Ages)	Below Poverty - 35.6% 1 to 2x Poverty - 29.3% 2 to 3x Poverty - 15.4% Over 3x Poverty - 19.7%
Employment Status (Adults, 18-64)	Employed - 56.5% Housekeeping - 15.2% School - 7.2% Unemployed - 12.1% Unable to work, early retirement - 8.9%
Age	0-17 - 33.0% 18-24 - 23.6% 25-44 - 27.4% 45-64 - 16.0%
Race (Adults)	White - 79.3% Black - 17.3% Other - 3.5%

*Percentages in each group may not add to 100.0% because of rounding. (adapted from M. SULVETTA & K. SWARTZ, *supra* note 11, *passim*).

C. Problems Posed by Lack of Coverage

1. Poor Access to Care and Poor Health for the Uninsured.— Uninsured people get less medical care, for a combination of reasons: they seek less care on their own, they are referred less often for specialized care or hospitalization, or they are turned away or otherwise discouraged by some providers.[27] The uninsured are far more likely not to have a regular source of care and much less likely to use medical services than are the insured, as Table 4 indicates.

[27]*See* Aday & Andersen, *The National Profile of Access to Medical Care: Where Do We Stand?*, 74 AM. J. PUB. HEALTH 1331 (1984); *see also* Davis & Rowland, *Uninsured and Underserved: Inequities in Health Care in the United States*, 61 MILBANK MEM. FUND Q. 149 (1983); ROBERT WOOD JOHNSON FOUNDATION, UPDATED REPORT ON ACCESS TO HEALTH CARE FOR THE AMERICAN PEOPLE (Special report no. 1, 1983). For a more rousing portrait of the uninsureds' problems, see Dallek, *Six Myths of American Medical Care: What the Poor Really Get*, HEALTH/PAC BULL., May-June 1985, at 9.

TABLE 4
HOW INSURANCE STATUS AFFECTS MEDICAL CARE

Indicator of Medical Use	Insured	Uninsured
Physician visits per person under age 65 in 1977	3.7	2.4
Hospital patient days per 100 persons under age 65 in 1977	90.0	47.0
Families who needed care but did not receive it in 1982	4.8%	15.0%
Families who did not see a physician in 1982	17.1%	32.9%
People with no regular source of health care in 1982	9.7%	23.1%

(adapted from M. SULVETTA & K. SWARTZ, *supra* note 11, at 4 (citing Davis & Rowland, *supra* note 27; ROBERT WOOD JOHNSON FOUNDATION, *supra* note 27)).

It is undocumented to what extent reduced access to care hurts the health of the uninsured, but it is reasonable to assume that their health does suffer.[28] Thus, the uninsured are generally thought to be sicker than the insured, a difference probably reflecting not only reduced medical attention as such but also low income, inability to work, depression from unemployment, and possibly other factors as well.[29]

2. *Uncompensated Care for Providers.*—Much of the recent concern over lack of health coverage derives from hospitals' fears of "uncompensated care," which is a frequent result of treating uninsured persons.[30] Uncompensated care consists of both charity care (provided to the indigent with no expectation of payment) and "bad debts" (unpaid bills of those expected to pay).[31] In 1982, about five or six percent of total hospital charges went uncompensated.[32] Because aggregate hospital charges

[28]*See generally* Mundinger, *Health Service Funding Cuts and the Declining Health of the Poor*, 313 NEW ENG. J. MED. 44 (1985).

[29]Empirical evidence on this point is weak. *Cf. id.* (loss of access to medical care hurts health); Davis & Rowland, *supra* note 27, at 165-66 (15% of uninsured rate health as fair or poor, vs. 11% of insured; sick uninsured have 4.1 physician visits annually, vs. 6.9 for sick insured).

[30]*See generally* UNCOMPENSATED HOSPITAL CARE: RIGHTS AND RESPONSIBILITIES (F. Sloan, J. Blumstein & J. Perrin eds. 1986) [hereinafter UNCOMPENSATED HOSPITAL CARE].

[31]It does not include "contractual allowances" or "discounts" below charges or costs that some hospitals give to some insurers' patients by virtue of participation agreements (as for Blue Cross/Blue Shield plans in many areas) or special negotiations (as for "preferred provider" arrangements under which hospitals trade a discount for more insured patients). Sloan, Valvona & Mullner, *Identifying the Issues: A Statistical Profile,* in UNCOMPENSATED HOSPITAL CARE, *supra* note 30, at 16.

[32]M. SULVETTA & K. SWARTZ, *supra* note 11 at 25; Sloan, Valvona & Mullner, *supra* note 31, at 16, 19. The latter put 1982 uncompensated hospital care at $6.2 billion, or 5 percent of charges, and 6 percent of total receipts; using different survey data, the former put the 1982 level at $7.5 billion.

exceed costs or revenues, the percentage of uncompensated care is about a percentage point lower when expressed as a fraction of hospital budgets.[33]

The burden of uncompensated care is not spread evenly across providers. Public hospitals provide a vastly disproportionate amount of uncompensated care (40.1% of uncompensated charges, double their 19.0% share of total charges), as do major teaching hospitals (35.8% of uncompensated charges vs. 24.0% of total charges), and large city hospitals generally (49.1% of uncompensated charges vs. 39.1% of all charges).[34] Whether for-profit hospitals contribute their "fair share" relative to similar not-for-profit community hospitals is hotly debated.[35]

It is not reliably known what share of uncompensated hospital care goes to indigents. Charity is said to constitute about one third of uncompensated care,[36] but there is no single accepted operational definition of "charity care." Existing accounting practices allow hospitals discretion in applying classification standards for charity care, and reported charity varies by hospital.[37] Thus, there is no guarantee that reported hospital "charity" accords with social expectations or public desires with regard to the medically indigent.[38]

How is "uncompensated care" financed? After all, institutions like hospitals cannot give charity without themselves incurring costs. Individual professionals can donate "free" personal attention, time, and skill beyond normal working hours. But hospital care involves ancillary services, supplies, or multiple personnel which must be paid for with revenue from some source.

The conventional wisdom is that hospitals cross-subsidize nonpaying

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[33]*See supra* note 32. According to data collected by the American Hospital Association, this amount increases to 5.6% by 1984. *See infra* note 61.

[34]M. SULVETTA & K. SWARTZ, *supra* note 11, at 28, 31, 30.

[35]*See generally* FOR-PROFIT ENTERPRISE IN HEALTH CARE 97-126, 209-23, 225-32 (B. Gray ed. 1986) [hereinafter FOR-PROFIT-ENTERPRISE] (asserts that for-profit hospitals do not contribute enough). *But see* Sloan & Becker, *For-Profits v. Non-Profits: A Phantom Issue*, TECH. REV., April 1984, at 11.

[36]*See, e.g.*, Cohodes, *America: The Home of the Free, the Land of the Uninsured*, 23 INQUIRY 227, 228 (1986) (charity care comprises one-third of uncompensated care); *see also* Sloan, Valvona & Mullner, *supra* note 31, at 19 (of 1982's $6.2 billion in uncompensated charges, hospitals designated $1.7 billion as charity, $4.5 billion as bad debt).

[37]FOR-PROFIT ENTERPRISE, *supra* note 35, at 102; Sloan, Valvona & Mullner, *supra* note 31, at 19. More defined descriptions do exist for Hill-Burton purposes. *See infra* notes 121-31.

[38]In fairness to hospitals, it must be noted that there is little consistency in public programs' definition of indigency for purposes of eligibility determinations. One of few existing uniform standards is that established by the federal Department of Health and Human Services—belatedly, under pressure of repeated litigation—to measure hospitals' adherence to Hill-Burton requirements to deliver "free" care to indigents. *See* FOR-PROFIT ENTERPRISE, *supra* note 35, at 102. *See also infra* notes 121-28 and accompanying text.

patients largely with revenues earned from paying patients, especially those who pay hospital charges (or whose insurers do), since charges are higher than costs.[39] Lesser sources of revenue include philanthropic contributions, nonpatient revenues—both relatively minor for most hospitals—and, mainly for public institutions, direct public subsidies from tax funds.[40]

Alternatively, a hospital can subsidize uncompensated care from its own capital, incurring a deficit met largely by not funding depreciation. This last option obviously hurts the long-run viability of an institution and may impair its ability to raise operating capital as well. In 1980, fully one-third of the hospitals that provided a high volume of care to poor people were fiscally "stressed" in that they had deficits in operating and total accounts.[41]

Little is known about what care the uninsured indigent receive outside of hospitals, although it seems likely that non-hospital providers render relatively less uncompensated care than do hospitals.[42] For society at large, hospital service comprises some forty-six percent of personal health care spending (exclusive of public health activities, medical research, and construction); the balance goes to physicians, other professionals, drugs, nursing homes, and so on.[43] Hospitals, especially public ones, are the traditional "providers of last resort," and their legal obligations to provide care are greater than those of other providers.[44] Moreover, hospital care is the most heavily insured, which traditionally has given hospitals more "third-party" revenues from which to cross-subsidize charity care.

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[39]*See, e.g.*, FOR-PROFIT ENTERPRISE, *supra* note 35, at 106-07; Phelps, *Cross-Subsidies and Charge Shifting in American Hospitals*, in UNCOMPENSATED HOSPITAL CARE, *supra* note 30, at 108. It is often argued that cost-paying "insurers," especially Medicare and Medicaid, do not contribute to this shift. *See, e.g.*, J. MEYER, PASSING THE HEALTH CARE BUCK: WHO PAYS THE HIDDEN COST? (1983).

[40]FOR-PROFIT ENTERPRISE, *supra* note 35, at 100, Table 5.2, & 106 (public subsidy of $1.9 billion in 1984).

[41]Hadley, Mullner & Feder, *The Financially Distressed Hospital*, 307 NEW ENG. J. MED. 1283 (1982). This study focused on hospitals for which uncompensated care plus Medicaid constituted 24% or more of charges.

[42]The only estimates of non-hospital charity with which the authors are familiar confirm this expectation. One estimate holds that physicians provided some $2.9 billion of free care in 1982. *See* G. BAZZOLI, HEALTH CARE FOR THE INDIGENT: LITERATURE REVIEW AND RESEARCH AGENDA FOR THE FUTURE (1985). *But see* F. SLOAN, J. VALVONA & G. HICKSON, ANALYSIS OF HEALTH CARE OPTIONS IN TENNESSEE: UNCOMPENSATED CARE (Vanderbilt Univ. 1985) (Tennessee doctors provided only one-seventh the amount of uncompensated care as Tennessee hospitals).

[43]Levit, Lazenby, Waldo & Davidoff, *National Health Expenditures, 1984*, HEALTH CARE FINANCING REV., Fall 1985, at 1, 9 [hereinafter *National Health Expenditures*] (in 1984, hospital care claimed $157.9 billion out of $341.8 of personal health care).

[44]*See infra* text accompanying notes 101-31.

Uncompensated care is clearly a multibillion dollar problem for hospitals, presumably a smaller one for other providers. It is likely to have totalled about $10 billion in 1982 (assuming that two-thirds or three-quarters of it occurred in hospitals). The volume of uncompensated care has probably grown since then, as the next subsection discusses; certainly, the pressures on hospitals have increased.[45]

D. Growing Problems

Recent developments have made access to insurance and care more difficult for the medically indigent. Not only has the number of uninsured grown through 1984 (Table 1), but it is likely to continue to rise in the long run, despite a generally improved economy. A number of portents point in this direction. First, the normal, "structural" level of unemployment, below which the percentage of people looking for work is not apt to fall, even in good times, seems to have risen above the expected 3-4% of the 1970's to perhaps 5-6% or more. Few of the unemployed have employer-paid health coverage.[46] Second, employment patterns also seem to be undergoing a structural shift. To oversimplify, the United States is moving from manufacturing to service jobs, from unionized to nonunionized work forces, from mainly full-time to increasingly part-time workers, and from large employers to smaller ones—all moves from well-insured types of employment to less well-covered ones.[47]

Finally, the recent federal tax reform bill[48] reduces the incentives for companies and workers alike to shelter income in tax-free benefits like health insurance. Business in the aggregate will be paying considerably more federal income tax (although at a lower official marginal rate), which should make companies even more zealous about cutting corporate

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[45]Large as $10 billion may seem, it is not large in relation to some 31 million uninsured people in 1982 (*see supra* Table 1). Per capita, that amounts to little more than $300 for the year, far less than 1982's $1,184 per capita spending for the general population. *National Health Expenditures*, *supra* note 43, at 16. It may be safely assumed that this amount of charity care did not meet all the medical needs of the medically indigent, given the extent to which the uninsured receive less care (*see supra* Table 4). Meeting those needs on a prepayment basis would be substantially more costly. *See infra* notes 257-58.

[46]*See supra* note 20.

[47]Black, *Comment on "The Employed Uninsured and the Role of Public Policy,"* 23 INQUIRY 209 (1986); Monheit, *supra* note 24. Black's and Monheit's observations rest mainly on 1977 data about employment and insurance coverage. Unpublished research on changes in insurance status during 1980-86 by Stephen M. Long and Jack Rodgers of the Congressional Budget Office disputes some of the details of these findings, arguing that long-term structural changes do not explain the rapid rise in the number of uninsured in the early 1980's.

[48]Tax Reform Act of 1986, Pub. L. No. 99-514, 100 Stat. 2085; *Summary of Conference Agreement on H.R. 3838,* TAX NOTES, Sept. 8, 1986, at 985.

health benefits than they have already been.[49] Individuals will pay less federal tax overall, and at lower marginal rates, especially at the high and low ends of the scale. High-income and low-income taxpayers alike will thus find tax-free health benefits considerably less attractive than before, compared with the alternative of higher cash income.

At the same time, the cost of offering workplace health benefits has been raised by numerous government requirements in the form of "mandated benefits," thus making insurance benefit packages richer for some[50] and more available to others, including the recently unemployed and divorced dependents.[51] These developments are helpful in some regard to those already in well-insured positions but, again, do not ease the difficulties of the marginal company and its workers in attempting to get affordable health coverage. All of these trends seem to indicate that the future will see more people without health coverage, not fewer.

Meanwhile, uncovered people also seem to face even greater problems in obtaining care—especially if they cannot prepay in cash, at least in part. The main reason is that the ability of hospitals to cross-subsidize care to the indigent seems to be declining. All providers, including hospitals, face increased price competition from their competitors as well as greater price resistance from their customers. Both developments have adverse implications for the uninsured, at least in the short run.[52]

Hospitals generally seem to manage the extent to which they provide uncompensated care in order to match their fiscal capacity.[53] It is safe to assume that they will cut back if increased price competition threatens their earnings or their ability to attract paying patients. Cutback strategies will include choosing locations and services attractive to insured rather than uninsured populations, avoiding services like obstetrics and emergency treatment of trauma that often go uncompensated, and screening out or transferring indigents or requiring deposits from them, at least for non-emergency care.[54]

Although almost all hospitals provide some level of charity care, in most locations the institutional provider of last resort, if one exists, is the public hospital. Anecdotal evidence indicates that the demand for

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[49]*See supra* notes 22 & 23.

[50]State laws regulating insurance have for a decade or more been altered to require insurance plans to include mental health benefits, among others. One estimate is that nearly 600 such statutes exist. Demkovich, *Covering Options Through Mandated Benefits*, BUS. & HEALTH, Jan./Feb. 1986, at 27 (more than 580 laws at the end of 1984, requiring coverage of everything from alcoholism services, in 38 states, to hospices, in 5 states, with an almost equal number of new bills pending).

[51]*See infra* note 207 on the federal "COBRA" entitlements allowing continuance as a group member even after layoff, divorce, or other separation from the group.

[52]*See, e.g.*, Kinzer, *Care of the Poor Revisited*, 21 INQUIRY 5 (1984).

[53]Hadley, Mullner & Feder, *supra* note 41.

[54]FOR-PROFIT ENTERPRISE, *supra* note 35, at 104-05.

public hospital care has risen, in part as a result of transfers from other hospitals.[55] At the same time, state and local governments that traditionally have funded public hospitals' net deficits (after collections from Medicaid and other third-party payers) often have found themselves under considerable fiscal pressure, in the aftermath of recession and the "taxpayers' revolt."[56] Indeed, a number of public hospitals have closed since the late 1970's, perhaps most notably Philadelphia's,[57] and there is some movement toward "privatizing" others.[58]

For the future generally, some observers predict closures of as many as one thousand of today's six thousand short-term general hospitals, both public and private.[59] The remaining hospitals will have to be more concerned with competition for paying patients and less concerned about indigent care (which raises prices). Thus, in the 1990's, it is quite possible that the medically indigent will have less access to care than they do now, unless there are changes in public policy.

As a political matter, it seems undeniable that hospitals—not the indigent themselves—will continue to be largely responsible for making "uncompensated care/indigent care" a legislative issue.[60] The American Hospital Association has recently completed a report on indigent care, and almost every state has commissioned a task force on the topic.[61] In this way, hospitals can provide an effective political voice for their largely disenfranchised poor patients.[62]

For the moment, neither the administration nor the Congress seems inclined to assist in finding solutions, certainly not solutions that require

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[55]*See, e.g.*, Schiff, *supra* note 5.

[56]*See, e.g.*, *There's Life Yet in Tax Revolt*, THE ECONOMIST, Aug. 30, 1986, at 18.

[57]Reportedly, 111 nonfederal, short-term general hospitals, 19 of which were state or local institutions, closed between 1980 and 1982. Sloan, Valvona & Mullner, *supra* note 31, at 26.

[58]Bovbjerg, Held & Pauly, *Privatization and Bidding in the Health Care Sector*, 6 J. POL'Y ANALYSIS & MGMT. (1987) (forthcoming).

[59]*See, e.g.*, Mullner & McNeil, *Rural and Urban Hospital Closures: A Comparison*, HEALTH AFF., Fall 1986, at 131.

[60]*See, e.g.*, Richards, *Special Interests Push Indigent Care Solutions*, HOSPITALS, Oct. 16, 1984, at 106.

[61]AMERICAN HOSPITAL ASS'N, COST AND COMPASSION: RECOMMENDATIONS FOR AVOIDING A CRISIS IN CARE FOR THE MEDICALLY INDIGENT, REPORT OF THE SPECIAL COMMITTEE ON CARE FOR THE INDIGENT (1986). Most of the state studies consider their topic as much "uncompensated care" as "indigent care." For a summary of state studies during 1982-84, see J. LUEHRS & R. DESONIA, A REVIEW OF STATE TASK FORCE AND SPECIAL STUDY RECOMMENDATIONS TO ADDRESS HEALTH CARE FOR THE INDIGENT (1984) (responses of 21 states to survey); *see also* NAT'L CONF. OF STATE LEGISLATURES, 12 QUESTIONS: WHAT LEGISLATORS NEED TO KNOW ABOUT UNCOMPENSATED HOSPITAL CARE (undated, issued 1985).

[62]*See, e.g.*, Law, *A Consumer Perspective on Medical Malpractice*, 49 LAW & CONTEMP. PROBS. 305, 307 (1986).

new federal funding.[63] As a result, states and localities are scrambling to find new ways to bear the burden of financing care for the medically indigent.[64] This Article next considers the legal obligations for providing or financing care and concludes with an examination of state policy options for aiding the medically indigent.

III. Legal Rights to Health Care or Coverage

A. Rights and Responsibilities

The supply of medical care for the medically indigent may be diminishing, but there is no shortage of statements that medical care is a basic human "right." Religious leaders, moral philosophers, politicians, and even some judges have been heard from on this score.[65] Existing commentary on the subject is voluminous[66] and will not be reviewed here. Many arguments about rights occur on an abstract, philosophical plane. One underlying ethical-legal issue is whether society or medical

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[63]In post-Gramm-Rudmann Washington, concern over reducing the massive federal deficit seems to preclude new funding initiatives. The administration has repeatedly attempted to cut existing indigent health programs like Medicaid, *see* R. Bovbjerg & J. Holahan, *supra* note 18, and community health centers, *see* G. Peterson, R. Bovbjerg, B. Davis, W. Davis, E. Durman & T. Gullo, The Reagan Block Grants: What Have We Learned (1986) [hereinafter G. Peterson]. Congress has protected the basic scope of Medicaid and some other existing programs, but seems unwilling to fund new ones. It will consider mandates for employer or state contributions, but not new federal taxes. Thus, COBRA requires employers to offer group insurance continuation benefits. *See infra* note 207. "Risk pool" legislation seriously considered but not passed would have required states to help pay for "insurance of last resort" for the otherwise uninsured. Access to Health Care Bill, S. 2402, 99th Cong., 2d Sess., 132 Cong. Rec. S5218 (1986) discussed *infra* at note 290.

[64]*See supra* notes 7 & 61; *infra* note 136.

[65]*See, e.g.*, The Labor Day Statement of Cardinal John J. O'Connor on "The Right to Health Care" ("Every person has a basic right to health care which flows from the sanctity of life and the dignity of human persons" (citing 1981 Pastoral Letter on Health Care from American Catholic Bishops)), *excerpted in* Health/PAC. Bull., July/Aug. 1985, at 6-7; Williams, *The Idea of Equality*, in Philosophy, Politics, and Society 121-22 (P. Laslett & W. Ronciman eds. 1962) (It is a "necessary truth" that "the proper ground of [medical] treatment is need"); E. Kennedy, In Critical Condition (1972) (especially Chapter 10, Good Health Care: A Right for All Americans); Memorial Hosp. v. Maricopa County, 415 U.S. 250, 259 (1974) (dictum) ("[M]edical care is as much 'a basic necessity of life' to an indigent as welfare assistance. And . . . of greater constitutional significance. . . .").

[66]*See, e.g.*, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Securing Access to Health Care, Volume Two: Appendices, Socioculture and Philosophical Studies (1983) (twelve articles on access and right to it, each referencing various literatures); Fried, *Equality and Rights in Medical Care*, in Implications of Guaranteeing Medical Care 3 (J. Perpich ed. 1975).

providers owe the same care to all or whether charitable obligations are limited to some "decent minimum" of care.[67] Legal and policy analysis must consider how any such rights are determined and what, if any, corresponding responsibility attaches.

The most fundamental right to health care would be one derived from federal constitutional provisions. The constitutional authority of the federal government to fund health care for the medically indigent is indisputable,[68] and the federal-state Medicaid program is tangible evidence of that authority.[69] The government may assume by statute an obligation to fund medical care, but it has no general constitutional duty to do so. For example, the government may cut back previously offered Medicaid benefits[70] and may refuse to fund certain care, even care considered by some to be medically necessary.

The abortion cases well illustrate the distinction between a patient's right to receive care and a public obligation to pay for it. A patient's right to receive an abortion cannot be unduly restricted by government, but this limited right carries no corresponding funding obligations.[71] Government may even deny funds for abortions while paying for similar treatments under Medicaid or other programs.[72]

Two limited exceptions prove this rule. First, people involuntarily confined to mental institutions may have a "right to treatment" grounded in substantive due process or even in the eighth amendment's prohibition of cruel and unusual punishment. A number of lower federal courts have so held in cases of involuntary civil commitment.[73] The remedy for institutionalization without adequate treatment is not easily framed,

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[67]*Compare, e.g.*, PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL RESEARCH, SUMMING UP: FINAL REPORT ON STUDIES OF THE ETHICAL AND LEGAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIOR RESEARCH 29-30 (1983) ("The Commission proposes a standard of 'an adequate level of care' for all, not 'a right to health care' that offers patients access to all beneficial care, to all care that others are receiving, or to all that they need—or want.") *and* Fried, *supra* note 66 ("decent standard of care for all") *with, e.g.*, E. KENNEDY, *supra* note 65 (especially chapter 10, Basic Right of Access for All to Quality Care).

[68]U.S. CONST. Preamble ("promote the general welfare . . .").

[69]Social Security Act, tit. XIX, 42 U.S.C. §§ 1396 *et seq.* (1982 & Supp. 1985).

[70]Generally, states, rather than the federal government, are sued for implementing cutbacks, because most cutbacks have historically been undertaken at state discretion rather than by federal mandate. *See, e.g.*, Alexander v. Choate, 469 U.S. 287 (1985) (Tennessee cut of hospital coverage to 14 inpatient days held valid). In contrast, federal eligibility cutbacks in 1981 received no judicial challenge.

[71]Beal v. Doe, 432 U.S. 438 (1977); Roe v. Wade, 410 U.S. 113 (1973).

[72]Harris v. McRae, 448 U.S. 297 (1980).

[73]*See, e.g.*, Wyatt v. Aderholt, 503 F.2d 1305 (5th Cir. 1974); Rouse v. Cameron, 373 F.2d 451 (D.C. Cir. 1966), *appeal after remand*, 387 F.2d 241 (D.C. Cir. 1967); *Wyatt v. Stickney*: RETROSPECT AND PROSPECT (L. Jones & R. Parlour eds. 1981). *See generally* D. WEXLER, MENTAL HEALTH LAW: MAJOR ISSUES (1981).

but courts generally require either deinstitutionalization, sometimes also with treatment,[74] or improved institutional care, going beyond the merely custodial.[75] Determining precisely what care is required and at what cost proves rather difficult in practice.[76] The Supreme Court has given only limited support to even this narrow concept of a right to mental health treatment,[77] and the recent trend seems to disfavor such litigation.[78]

The second exception entitles incarcerated prisoners to adequate health care. Traditionally, what little health care was available in jails and prisons was very poor.[79] A series of lawsuits has established that prison inmates must be given at least that level of care that prevents their medical situation from being cruel and unusual punishment.[80] Again, precisely what level of care meets the constitutional minimum is not clear, nor is the extent to which a prisoner must contribute toward his own care.[81]

These two exceptions are readily understood. Both institutionalized mental patients and prisoners are individually made wards of the state. It is an easy step to hold that the act of taking away their liberty (and with it their capacity to help themselves or to seek private charity) requires the government to give them in return a reasonable level of medical care, along with humane treatment in other regards.[82] These

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[74]Callahan v. Carey, N.Y.L.J., Dec. 11, 1979, at 10, col. 5 (N.Y. Sup. Ct. Dec. 10, 1979).

[75]*See, e.g.*, *Wyatt v. Stickney*: RETROSPECT AND PROSPECT, *supra* note 73.

[76]*See id.*; *see also* Miller, *The "Right to Treatment": Can The Courts Rehabilitate and Cure?*, 46 THE PUBLIC INTEREST 96 (1977).

[77]*See, e.g.*, McNeil v. Director, Patuxent Inst., 407 U.S. 245 (1972) (holding that the state of Maryland could not confine appellant indefinitely on basis of administrative referral for observation under "defective delinquent" law; dictum noted remarkable rarity of litigation to set "substantive constitutional limitations on this [civil commitment] power").

[78]*See, e.g.*, Jones v. United States, 463 U.S. 354 (1983) (civil commitment of convicted criminal upheld despite not meeting standards for independent civil commitment); Youngberg v. Romeo, 457 U.S. 307 (1983) (constitutional "right to habilitation" grounded on deprivation of personal freedom and safety, not on extent of available medical treatment); Pennhurst State School v. Halderman, 451 U.S. 1, 18 (1982) (poorly treated mentally retarded patients not entitled to redress against the state under federal handicapped statute; Congress did not intend to require states "to assume the high cost of providing 'appropriate treatment' " in exchange for federal funds).

[79]*See, e.g.*, S. GOLDSMITH, PRISON HEALTH: TRAVESTY OF JUSTICE (1975).

[80]*See generally* Neisser, *Inmate Welfare Funds: Reassessing Prisoner Assessments*, in PRISONERS AND THE LAW 16-1, 16-18 through 16-20 (I. Robbins ed. 1985); Neisser, *Is there a Doctor in the Joint? The Search for Constitutional Standards for Prison Health Care*, 63 VA. L. REV. 921 (1977).

[81]In City of Revere v. Massachusetts General Hospital, 463 U.S. 239 (1983), the Supreme Court carefully refrained from deciding to what extent the hospital could collect from the patient, who was granted bail while hospitalized with wounds received during arrest, stating that this was a matter of state law. *Id.* at 245-46.

[82]*Cf.* Wyatt v. Aderholt, 503 F.2d 1305, 1312 (5th Cir. 1974) (treatment is "the *quid pro quo* society [has] to pay as the price of . . . denial of individuals' liberty").

exceptional cases do not support a fundamental *positive* "right to health care," but there may be a fundamental *negative* right allowing a sort of "free exercise." Thus, whereas certain aspects of medical practice are subject to restrictions under licensure or economic regulation,[83] courts have recognized the importance of professional freedom[84] and patients' free choice,[85] even the choice not to receive care of any sort.[86]

However, for the most part, the medically indigent have only those entitlements that have been voluntarily enacted, in whole or in part, to help them.[87] Each statute—Medicare, veterans' coverage, maternal and child health, and so on—carries with it greater or lesser entitlements to a more or less defined population. The negative implication of each program of special assistance is that no general federal obligation exists.

Beyond basic federal law, there are three other possible sources of indigent rights. These are the duties of providers, of states and localities, and of health insurers.

B. Obligations of Health Care Providers

1. Physicians. a. Duty to treat.—Although physicians may voluntarily provide charity care to the indigent, they have no affirmative legal duty to do so. Like anyone else, physicians are free not to render aid even in an emergency.[88] Any assistance that a physician may gratuitously render is considered the act of a "good samaritan."[89] This same view has been echoed by numerous courts across the nation, and stands unchanged by statute.[90]

Most legal doctrine on the subject arises from malpractice law, enforced through tort suits for damages. Doctors are remarkably free of legal duty to treat anyone, paying customers and the impecunious alike. The classic statement of this non-duty comes from *Hurley v.*

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[83]*See, e.g.* IND. CODE §§ 25-22.5-1-1 *et seq.* (1982).

[84]*Cf.* Roe v. Wade, 410 U.S. 113, 163 (1973) (importance of noninterference with doctors' judgment).

[85]The malpractice rule that patients must give "informed consent" is based on the importance of personal sovereignty. *See generally* J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984).

[86]*In re* Quinlan, 70 N.J. 10, 355 A.2d 647 (1976), is the seminal case. For a full discussion, see PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, DECIDING TO FORGO LIFE-SUSTAINING TREATMENT: ETHICAL, MEDICAL, AND LEGAL ISSUES IN TREATMENT DECISIONS (1983).

[87]On federal medical programs, see generally F. WILSON & D. NEUHAUSER, HEALTH SERVICES IN THE UNITED STATES 137-228 (2d ed. 1982).

[88]*See* RESTATEMENT (SECOND) OF TORTS § 314 comment c (1965).

[89]State law typically protects such medical samaritans from ordinary negligence actions. *See, e.g.*, IND. CODE §§ 34-4-12-1 to -2 (1982).

[90]*See e.g.*, Harper v. Baptist Medical Center-Princeton, 341 So. 2d 133 (Ala. 1976); Childers v. Frye, 201 N.C. 42, 158 S.E. 744 (1931); Lyons v. Grether, 218 Va. 630, 239 S.E.2d 103 (1977).

Eddingfield,[91] a turn-of-the-century case in which the Indiana Supreme Court ruled that a physician had no duty to treat anyone. The court saw no common law duty, even though the doctor was not otherwise occupied, the would-be patient was very sick (he later died), was a former patient of the refusing physician, and tendered payment in advance. The court rejected any medical analogy with the common law duty of innkeepers to serve all comers as well as the argument that the then recently enacted state regulatory scheme of physician licensure had created such a duty. This minimalist legal view of physicians' obligations to would-be patients has long been an accepted tenet of organized medicine as well as of the law.[92] The traditional rule that physicians are free to reject anyone as a patient may have been tempered somewhat by civil rights legislation,[93] but medical indigency is not a protected civil rights category.

A physician's legal duty to treat a patient arises only from mutual consent—by express contract or by one implied by the parties' behavior. Whether this contractual physician-patient relationship exists is a factual question that turns upon whether the physician accepted the case and whether the patient accepted the physician's professional services.[94] Under certain circumstances, some courts have inferred a duty to treat even absent specific consent. For example, an Arizona court ruled that a physician on the staff of a hospital who agreed to be an "on-call" emergency room doctor could no longer refuse treatment to an individual seeking emergency care.[95] A New York court found a physician-patient relationship based solely on a telephone conversation between a hospital physician and an emergency room visitor, even though the physician was said mainly to have directed the patient to see his own doctor.[96] For the most part, however, mutual consent remains a requirement.

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[91]156 Ind. 416, 59 N.E. 1058 (1901).

[92]Am. Med. Ass'n, Principles of Medical Ethics § 6 (1985); *cf.* Relman & Reinhardt, *An Exchange on For-Profit Health Care*, in For-Profit Enterprise, *supra* note 35, at 209 (lack of duty to serve shows profit orientation of physicians).

[93]*See generally* Nat'l Health Law Program, Manual on State and Local Government Responsibilities to Provide Medical Care for Indigents 163-71 (M. Dowell ed. 1985) [hereinafter State and Local Government Responsibilities] (Chapter IV, "Access to Health Care and Civil Rights Legislation").

[94]*Lyons*, 218 Va. 630, 239 S.E.2d 103; *see also* 61 Am. Jur. 2d *Physicians, Surgeons, and Other Healers* § 96 (1972).

[95]Hiser v. Randolph, 126 Ariz. 608, 617 P.2d 774 (Ariz. Ct. App. 1980), *overruled on other grounds*, Thompson v. Sun City Community Hosp., Inc. 141 Ariz. 597, 688 P.2d 605 (Ariz. 1984) (The court in *Thompson* also distinguished *Hiser* on the issue of the physicians' duty to treat in emergency situations). *But see, e.g.*, Wilmington Gen. Hosp. v. Manlove, 54 Del. 15, 174 A.2d 135 (1961); Richard v. Adair Hosp. Found. Corp., 566 S.W.2d 791 (Ky. Ct. App. 1978). *See infra* discussion at notes 112-20 on emergency care and duty to serve.

[96]O'Neill v. Montefiore Hosp., 11 A.D.2d 132, 202 N.Y.S.2d 436 (1960).

b. Standard of care and extent of treatment.—Once a patient-physician relationship has been established, the physician must exercise the same standard of care—customary skill and diligence[97]—regardless of whether the patient is an indigent or a paying customer. Even when physicians render their services gratuitously, their potential liability for negligence or malpractice remains the same as in treating any other patient.[98]

Having once begun treatment, a physician must continue treatment as long as medical care is necessary or face a possible malpractice action for abandonment if actionable damage occurs.[99] Physicians may safely withdraw from a case only when services are no longer needed, when the patient voluntarily terminates the relationship, when referral is made to an equally qualified practitioner, or when the patient has a reasonable opportunity to see another physician.[100]

2. Hospitals. a. Duty to treat.—As a general matter, private hospitals, like physicians, have no legal duty to accept all potential patients seeking care, except perhaps in emergency situations.[101] Public hospitals, by statute, by charter, or by tradition, generally are obligated to accept all patients, at least in emergencies,[102] but the "right" of admission to public hospitals for non-emergency cases is not absolute.[103]

Even more than that of physicians, hospitals' discretion to refuse patients is limited by civil rights provisions,[104] but in general, ability to pay can be considered in deciding whether to treat. Indeed, absent an emergency, a hospital may require a cash deposit as a condition of admission.[105] Significantly, in only about half of the states are hospitals

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[97]The classic article is McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549 (1959); *see also* A. HOLDER, MEDICAL MALPRACTICE LAW 40-43, 53-55 (1975).

[98]*See, e.g.*, Rule v. Cheeseman, 181 Kan. 957, 317 P.2d 472, 477 (1957) (the fact that the patient was a charity patient was immaterial in determining the surgeon's negligence); *see also* 70 C.J.S. *Physicians and Surgeons* § 52 (1951).

[99]*See, e.g.*, A. HOLDER, *supra* note 97, at 374-402.

[100]Lyons v. Grether, 218 Va. 630, 239 S.E.2d 103 (1977); *see also* Annotation, *Liability of Physician Who Abandons Case*, 57 A.L.R.2d 432, 439 § 3 (1958).

[101]*See, e.g.*, Birmingham Baptist Hosp. v. Crews, 229 Ala. 398, 157 So. 224 (1934) (physician in emergency room diagnosed child's advanced diphtheria and began treatment but hospital denied admission because the disease was contagious; held no liability for later death); Hill v. Ohio County, 468 S.W.2d 306 (Ky. 1971), *cert. denied*, 404 U.S. 1041 (1972) (pregnant woman had no right to hospital admission, absent emergency); *see also* A. SOUTHWICK, THE LAW OF HOSPITAL AND HEALTH CARE ADMINISTRATION 161-62 (1978).

[102]*See* Wilmington Gen. Hosp. v. Manlove, 54 Del. 15, 174 A.2d 135 (1961) (dictum on public hospital duty); A. SOUTHWICK, *supra* note 101, at 162-64.

[103]*See* A. SOUTHWICK, *supra* note 101, at 163.

[104]*See* STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, at 163-71.

[105]Joyner v. Alton Ochsner Medical Found., 230 So. 2d 913 (La. App. 1970) (auto accident victim given emergency treatment but refused admission).

legally required to have emergency rooms.[106]

As with physicians, once a hospital begins to provide diagnosis and treatment for an indigent patient, it is held to the same standard of care as for any other patient.[107] Particularly when financial considerations prompt an early discharge of a patient, the hospital may be found liable for damages in a tort suit for abandonment.[108]

However, tort actions constitute an abysmal enforcement tool for achieving access to care. Only those emergency refusals that result in compensable damages are normally actionable, and severe damage is usually needed to justify the expense of a suit. Indigents are also disadvantaged because their economic damages are likely to be low and they may have poor access to legal assistance.[109] Moreover, if indigents are receiving public assistance, they may not be allowed to keep much of any recovery.

Malpractice doctrine is, therefore, of little help to indigents seeking care.[110] Indeed, if anything, malpractice law may actually hurt indigents' access to private care, because offering any care may make a provider, especially a hospital, liable to provide all needed care, perhaps entirely without recompense. It is precisely this concern that presumably prompts "dumping."

One way to reduce the malpractice incentive to dump patients would be to grant immunity from tort actions to providers that conform to the coverage and utilization requirements of any applicable indigent care program. The existing federal Professional Review Organization (PRO) legislation provides such immunity with regard to the appropriateness

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[106]About half of states directly or indirectly require certain categories of hospitals to have emergency facilities. A. SOUTHWICK, *supra* note 101, at 183-84. *See, e.g.*, ILL. ANN. STAT. ch. 111 1/2, para. 86, 87 (Smith-Hurd 1977 & Supp. 1986) (private and public hospitals providing general medical or surgical services); PA. STAT. ANN. tit. 62, § 443.3 (Purdon 1986) (all hospitals receiving payments from Department of Public Welfare). STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, provides a table of emergency care laws; on tax rules, see *id.* at 489-90.

[107]HOSPITAL LAW MANUAL ¶ 1-3 (1981).

[108]*See e.g.*, Meiselman v. Crown Heights Hosp., 285 N.Y. 389, 34 N.E.2d 367 (1941) (hospital discharged patient when open wounds were still draining); Jones v. City of New York, Hosp. for Joint Diseases, 134 N.Y.S.2d 779 (N.Y. Sup. Ct. 1954), *rev'd on other grounds*, 286 A.D. 825, 143 N.Y.S.2d 628 (1955) (transfer of a stabbing victim who later died was for hospital convenience rather than necessity and thus actionable).

[109]The last point is not self-evident, given free legal assistance as a free point of entry and the wide availability of the private, contingent-fee personal injury bar. No direct evidence on this point seems to exist. The only major empirical analysis of medical malpractice, however, provides *indirect* evidence, that the incidence of claims does not vary by differences in per capita income or in the proportion of people on welfare among states. P. DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY 75 (1985).

[110]*See* Law, *supra* note 62, at 306-15; Rosenblatt, *Rationing "Normal" Health Care: The Hidden Legal Issues*, 59 TEXAS L. REV. 1401, 1410-15 (1981).

of treatment when Medicare has denied payment.[111] However, a broader immunity provision could apply equally to coverage issues as well as to issues of appropriateness. Under such a provision, a hospital would be immune from suit if it failed to provide uncompensated care beyond that covered under the indigency care program.

Of course, there are other ways to discourage providers from transferring patients, at least emergency patients, inappropriately. New federal legislation specifically addresses inappropriate transfers.

b. Emergency room as a source of duty to treat.—Under 1986 federal legislation, hospitals that operate emergency rooms and that participate in the Medicare or Medicaid programs must follow certain protocols in assessment, treatment, and transfer of emergency patients (including patients arriving in active labor).[112] The duty applies to all patients, not merely to public program beneficiaries.[113]

This legislation was passed in response to growing concern over refusals of care and "dumping" of patients on public facilities.[114] Basically, affected hospitals must examine all patients and then either accept them for full treatment or at least stabilize their condition so that they can be safely transferred. Unstabilized patients may be transferred only with their express consent or when the transfer is certified to be in their own interest.[115] The federal act specifically states that it does not preempt state rules except when they are plainly inconsistent with federal requirements.[116] Clearly the state remains free to enforce more stringent standards.

The federal act was in many ways modeled upon landmark Texas legislation that took effect the week before the federal action.[117] Under the Texas law, a physician must examine all emergency patients within

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[111]42 U.S.C. § 1320c-6(c) (1982). This little known and little used provision was also included in the predecessor PSRO legislation. It applies to Medicare, and to Medicaid as well where the state elects to use the PRO to perform Medicaid review.

[112]Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9121, 100 Stat. 82, 164 *et. seq.* (COBRA, approved Apr. 7, 1986). Almost all hospitals participate in one or both of these programs, and many have emergency rooms. *See supra* note 106.

[113]The legislation's constitutionality might be challenged on the ground that no legitimate purpose is served by requirements for non-Medicare persons as well as for Medicare beneficiaries. In defense, one could argue that it is unwise, in emergency circumstances, to make distinctions among various patients according to their insurance status.

[114]*See supra* notes 4 & 5.

[115]Specifically, transfers before stabilization or during active labor may occur only at the request of the patient or upon certification of the physician that the medical benefits expected from transferring outweigh the risks of effecting the transfer. In addition, transfers may be made only to facilities with available space and qualified personnel who have agreed to accept the transfer and to provide appropriate medical treatment.

[116]Consolidated Omnibus Budget Reconcilation Act of 1985, Pub. L. No. 99-272, § 9121, 100 Stat. 82.

[117]Texas Indigent Health Care and Treatment Act, TEX. REV. STAT. ANN. art. 4438f (Vernon Supp. 1986). *See* Chershov, *Texas Transfer Law Still Spurs Controversy*, HOSPITALS, May 5, 1986, at 160.

twenty minutes of their arrival. Patients are to be stabilized before any transfer, and the receiving hospitals and physicians must agree to the transfer.

In the absence of applicable statutory enactments, emergency treatment and transfer is governed mainly by malpractice law. In this connection, many state courts have held that operating an emergency room creates a duty to treat emergency cases regardless of payment.[118] However, not all courts have accepted the emergency room exception to the general no-duty rule,[119] and some have rejected it.[120]

c. The Hill-Burton Act as a source of duty to treat.—In the past, many hospitals have accepted federal capital grants or loans under the Hill-Burton program.[121] The terms of these grants obligate hospitals to provide a "reasonable volume" of free or below-cost services to persons unable to pay for hospital care. Until the 1970's, it was unclear exactly how much care hospitals were required to provide (i.e., what was a "reasonable volume") and to whom they were to provide it. In 1970, a federal district court found that a private civil action could be implied under the Hill-Burton Act because the Act was designed in part to benefit directly those persons unable to pay for medical services.[122] Upon review, the circuit court held that individual hospitals could not be expected to supply all the services needed by indigents in their states.[123]

Accordingly, the Secretary of Health, Education, and Welfare (now, the Secretary of Health and Human Services) issued clarifying regulations on what amount of uncompensated services provided by a hospital would constitute compliance with the "reasonable volume" requirement of the Hill-Burton Act. Even with continued litigation in the 1970's and the revised regulations,[124] the Hill-Burton Act has proven difficult to enforce.[125] Although the regulations and cases tend to interpret the Hill-

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[118]*See e.g.*, Hiser v. Randolph, 126 Ariz. 608, 617 P.2d 774 (Ariz. Ct. App. 1980); Wilmington Gen. Hosp. v. Manlove, 54 Del. 15, 174 A.2d 135 (1961); Mercy Medical Center of Oshkosh, Inc. v. Winnebago County, 58 Wis. 2d 260, 206 N.W.2d 198 (1973).

[119]*See, e.g.*, Campbell v. Mincey, 413 F. Supp. 16 (N.D. Miss. 1975) (dictum noting that *Manlove* not universally followed; held, no emergency, so hospital not liable under own rules).

[120]*See, e.g.*, Perth Amboy Gen. Hosp. v. Board of Chosen Freeholders, 158 N.J. Super. 556, 386 A.2d 900 (1978); Fabian v. Matzko, 236 Pa. Super. 267, 344 A.2d 569 (1975). *Compare* K. WING, THE LAW AND THE PUBLIC'S HEALTH 234-45 (2d ed. 1985) (hospital duty in emergency not settled law) *with* A. SOUTHWICK, *supra* note 101, at 185-89 ("[m]ost observers" think holding that emergency room creates duty "should now be accepted as the rule." *Id.* at 187).

[121]42 U.S.C. § 291(c)(e) (1982) (The Hospital Survey and Construction Act of 1946).

[122]Cook v. Ochsner Found. Hospital, 319 F. Supp. 603 (E.D. La. 1970), *aff'd*, 559 F.2d 968 (5th Cir. 1977).

[123]*Cook*, 559 F.2d at 971.

[124]42 C.F.R. § 124.503 (1979).

[125]*Cf.* Blumstein, *Court Action, Agency Reaction: The Hill-Burton Act as a Case Study*, 69 IOWA L.REV. 1227 (1984); Wing, *The Community Service Obligation of Hill-Burton Health Facilities*, 23 B.C.L. REV. 577 (1982).

Burton Act as creating entitlements for specific classes of patients,[126] no individual patient has a claim to free services.[127] Furthermore, even though the regulations define persons "unable to pay," each hospital may develop its own plans for distributing charity care.[128]

Some $571 million of free care met Hill-Burton obligations in 1984,[129] a figure well below the uncompensated care burden[130] and dwarfed by apparent need. Even this amount of charity care is likely to diminish in the future because Hill-Burton "free care" obligations normally last for twenty years and the grant program was virtually eliminated in 1974.[131]

C. Obligations of States and Localities

All states and a great many political subdivisions (counties, towns, or cities) voluntarily provide or finance a variety of health services. The largest program by far is the federal-state Medicaid program. Participating states, by federal requirement, must cover certain categorically eligible poor people and must provide certain mandatory benefits. Additional coverage may be added at a state's option within the limits of federal financial participation.[132] Medicaid's contribution to preventing medical indigency is well known. Medicaid programs have by and large ceased to expand to cover many additional people.[133] Consequently, this Article does not further describe Medicaid at this point.

All levels of government provide many specialized health services for the general population and general services for specialized populations. Classic examples are treatment or immunizations for communicable diseases and care for handicapped children.[134] Poor people often receive

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[126]Blumstein, *supra* note 125.

[127]Newsom v. Vanderbilt Univ., 653 F.2d 1100, 1121 (6th Cir. 1981).

[128]42 C.F.R. § 124.507 (1979).

[129]STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, at 35.

[130]Sloan, Valvona & Mullner, *supra* note 31, at 19 ($1.7 billion of hospital-denominated charity care is included in the $6.2 billion of uncompensated care).

[131]U.S. OFF. OF MGMT. & BUDGET, THE BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 1975, APPENDIX 415 (1974).

[132]*See generally* R. BOVBJERG & J. HOLAHAN, *supra* note 18.

[133]*See generally* J. HOLAHAN & J. COHEN, *supra* note 18. An exception is limited expansions targeted at needy children and young mothers, including expectant mothers, authorized by 1986 federal legislation. *See infra* note 224.

[134]*See generally* F. GRAD, PUBLIC HEALTH LAW MANUAL (1973); ROLE OF STATE AND LOCAL GOVERNMENTS IN RELATION TO PERSONAL HEALTH SERVICES (S. Jain ed. 1981) [hereinafter ROLE OF STATE AND LOCAL GOVERNMENTS] (reprinted from 71 AM. J. PUB. HEALTH 1 (Supp. Jan. 1981)). STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, cites statutory authority for many of these programs. The Association of State and Territorial Health Officials (ASTHO), through its Public Health Foundation, publishes several annual compilations of data on public health activities reported by 57 state health agencies and estimated for some 3,000 local health departments. *See, e.g.*, PUBLIC HEALTH FOUNDATION, 1984 PUBLIC HEALTH CHARTBOOK (1986).

particular emphasis in such programs, but they are not the focus. Moreover, this type of public health activity tends to be quite restricted, both in the scope of the care provided and in the level of financing made available.[135] Consequently, this Article also skips over programs such as these to consider in depth only direct efforts to curb medical indigency.

1. Sources of State Power to Provide Indigent Health Care.[136]—All but three states either authorize or require state or county governments to provide for "relief and support" of the poor.[137] Many of these laws date from 19th century "poor laws."[138] The older statutes do not always expressly mention medical care, but several have been interpreted to cover at least some level of medical services.[139] State authority to provide or finance health care is derived from the general police power.[140] Counties (or other substate jurisdictions) have such power by virtue of delegation from their states.[141]

2. Types of Local Indigent Health Programs.—Existing indigent care programs can be divided into four different types: The first is the public hospital model, most typically run by counties or cities, sometimes with state aid. States using this approach operate hospitals themselves or authorize counties to do so. These public hospitals are generally required to serve the poor free or at a discount.[142] In 1984, there were

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[135]In fiscal year 1984, for example, state and local public health spending totaled some $6.5 billion. PUBLIC HEALTH FOUNDATION, *supra* note 134, Fig. 1. A few state health agencies administer Medicaid in their states, but the latter expenditures are not included. By way of comparison, federal-state expenditures for Medicaid in 1984 totalled $34.5 billion (provider payments only). J. HOLAHAN & J. COHEN, *supra* note 18, at 9.

[136]The following discussion owes much to three legal and programmatic compilations of information on assistance for the medically indigent. Butler, *Legal Obligations of State and Local Government for Indigent Health Care*, in ACADEMY FOR STATE AND LOCAL GOVERNMENT, ACCESS TO CARE FOR THE MEDICALLY INDIGENT: A RESOURCE DOCUMENT FOR STATE AND LOCAL OFFICIALS 13-44 (R. Curtis & S. White eds. 1985) [hereinafter ACADEMY] provides the most readable review. STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, thoroughly documents existing programs from the perspective of legal enforcement; it gives numerous state-by-state listings, extracts and commentaries. INTERGOVERNMENTAL HEALTH POLICY PROJECT, GEORGE WASHINGTON UNIV., STATE PROGRAMS OF ASSISTANCE FOR THE MEDICALLY INDIGENT (1985) [hereinafter IHPP] also gives state-by-state profiles from the program point of view, as well as some fiscal data. This Article would not have been possible without the kind of background provided by such data sources.

[137]Kentucky, North Carolina, and Tennessee have no unit of government legally responsible for indigent health care. Butler, *supra* note 136 at 17, Table I.

[138]New Hampshire's General Assistance program, for example, originated from English Poor Laws. Baker-Chaput v. Cammett, 406 F. Supp. 1134, 1137 (D.N.H. 1976). *See also* R. STEVENS & R. STEVENS, WELFARE MEDICINE IN AMERICA (1974).

[139]*E.g.*, Jerauld County v. St. Paul-Mercury Indem. Co., 76 S.D. 1, 71 N.W.2d 571 (1955); *see, e.g.*, Butler, *supra* note 136, at 16.

[140]Jacobson v. Massachusetts, 197 U.S. 11 (1905); Industrial Comm'n v. Navajo County, 64 Ariz. 172, 167 P.2d 113 (1946); *Jerauld County*, 76 S.D. 1, 71 N.W.2d 571.

[141]*Jacobson* 197 U.S. 11; F. GRAD, *supra* note 134.

[142]States that have used this method include Arkansas, Colorado, Florida, Iowa, Maine, Michigan, Missouri, Nevada, North Carolina, South Carolina, West Virginia, and Wisconsin. Butler, *supra* note 136, at 19 n.25.

some 1,622 state and local government hospitals, of a national total of 5,759 community hospitals.[143] These hospitals are important not merely for inpatient care but also for outpatient care in emergency rooms and outpatient clinics, especially in the nation's large urban areas.

A second approach is for government to contract for indigent care with specific private providers, mainly hospitals and community health centers but occasionally individual practitioners as well. Several levels of government may share financing.[144] Contracting is common for public health and mental health services and is sometimes used for general health care to the indigent.[145] States that have used this approach include Colorado, Delaware, Florida, Idaho, and Indiana.

The third and fourth methods are both more insurance-style medical programs, under which eligible indigent enrollees can get specified services from many providers, not merely one or a few contracting providers. Model number three is a rather limited "vendor-payment" program under which eligibles do not enroll in advance. Medical providers bill the county or state for care to the indigent and are reimbursed at some rate on a case-by-case basis.[146] The benefits available and the indigency standards for such programs vary greatly from place to place. Often, only hospital care is covered.

Model four is the more familiar style of insurance program that resembles Medicaid or private insurance: Once eligible persons enroll, they may seek any covered service (typically well beyond hospital care) from any participating provider. A few states provide full Medicaid benefits to the medically indigent, wholly at their own expense, without federal matching support.[147] More commonly, these insurance-style programs for indigent care are far more restricted than Medicaid, both in

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[143] AM. HOSP. ASS'N, HOSPITAL STATISTICS 7, Table 1 (1985) (data from 1984 survey). An additional 700-odd institutions were federal or long-term hospitals. Although state and local hospitals thus constituted 28% of the total, they contributed a smaller share of total hospital beds, some 20% in 1984. On public hospitals' contributions to indigent care, see e.g., Dallek, *The Continuing Plight of Public Hospitals*, 16 CLEARINGHOUSE REV. 97 (1982); Feder, Hadley & Mulliner, *Poor People and Poor Hospitals*, 9 J. HEALTH POL. POL'Y & L. 237 (1984).

[144] Community health centers often receive a mix of federal block grant, state, and local funding to supplement earnings from charges to patients and their insurers, if any. *See, e.g.*, G. PETERSON, *supra* note 63; R. PRICE, HEALTH BLOCK GRANTS (1981).

[145] On public health contracting, see, e.g., Jain, *supra* note 134. Iowa contracts with the University of Iowa Hospitals and Clinics to provide non-Medicaid indigent health care statewide. IHPP, *supra* note 136, at 139. For a list of citations to states using this approach, see Butler, *supra* note 136, at 20 nn.28-30.

[146] *See* Butler, *supra* note 136, at 28-30; STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93.

[147] Maryland's indigent care program is its Medicaid program, for example. IHPP, *supra* note 136, at 157.

benefits and in provider payment levels.[148] Eligibility for these indigency programs may be tied to receipt of state "general assistance" (welfare), just as Medicaid categorical eligibility is based on welfare (Aid to Families with Dependent Children or Supplemental Security Income Assistance). This subtype of insurance program is often called a "GA-medical" program.[149] Administrative and funding responsibilities for these insurance-style programs are often shared among state and local authorities.[150]

This brief discussion illustrates how widely the method of providing indigent care and coverage varies nationwide. In addition, the states differ in the amount of discretion they give to the financing or administrative agency. Some programs provide little administrative structure and few operational guidelines, whereas others are quite detailed and specific, and their diversity is enormous.[151]

From the point of view of the otherwise uninsured medically indigent, what matters about these state and local efforts is how much access to care they provide. The medical access that a program achieves depends on its legal requirements, the funding provided, and the administrative discretion given to allow funding to be matched to indigents' requirements. The administrator's discretion may be guided only by general statutory principles; or specific statutory or administrative provisions may govern eligibility, benefits, and level of provider payments.

3. Nature of State-Local Duty.—Although almost all states have statutes permitting publicly provided indigent health coverage or care,[152] few seem to mandate such aid. It has been argued that two states' constitutions require those states to provide for the poor, while three others require counties and hospital districts to do so.[153] But even these apparent constitutional mandates are open to interpretation about the nature of duty created.[154] In addition to constitutional provisions, some state statutes purport to impose duties on the state,[155] but these apparent "mandates" seem binding only so long as the state voluntarily accepts that duty. The state remains free to repeal a statute, even if by its terms it does not seem to allow administrative or budgetary cutbacks. Thus,

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[148]*Id. passim.*

[149]*Id.* at 26 (also called general relief, home relief, or poor relief).

[150]Butler, *supra* note 136, at 19.

[151]IHPP, *supra* note 136, at 67-292; *see also* STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93.

[152]*See, e.g.*, LA. REV. STAT. ANN. § 40:2017 (West 1977) (state department of health "may" provide for indigent care in private hospitals).

[153]Butler, *supra* note 136, at 16 nn.8, 9 (citing ALA. CONST. art. IV, § 88, KAN. CONST. art. 7, § 4, MONT. CONST. art. XII, § 3(3), N.Y. CONST. art. VIII, § 1 (states); TEX. CONST. art. 9, §§ 4,5,9. (counties or districts)).

[154]*See, e.g.*, MONT. CONST. art. XII, § 3 (state must establish institutions but only such as the public interest *may* require).

[155]*See, e.g.*, DEL. CODE ANN. tit. 31, § 505(6) (1985) (general assistance program).

it seems fair to conclude that there is no fundamental state right to health care; some courts have so held.[156]

On the other hand, state statutory mandates on lesser jurisdictions can be truly binding.[157] Some state courts have interpreted even ostensibly permissive statutes to mandate local government to fund care for the indigent. The Arizona Supreme Court, for example, read two statutes authorizing counties to care for the sick as imposing a duty to provide medical care for the indigent sick.[158] The obligation to provide some variety of indigent medical care may even appear in a city charter[159] and may apply even though an area is otherwise granted "home rule."[160] In some thirty-seven states, counties or towns are to some degree responsible for indigent care (often shared among levels of government); in four other states, counties are responsible for care only if they operate county hospitals.[161]

Public hospitals are generally required to serve the poor at a discount or at no charge. An interesting issue arises where administration of the public hospital is contracted out to a private firm (as increasingly occurs for cost containment reasons) or where the entire hospital is sold to private interests. Of course, the private administrators or new owners may be obligated by contract to provide some level of indigent care. North Carolina has gone even further, enacting a provision requiring both purchasers and lessees of public hospitals to continue indigent care.[162] In any event, enforcement of any such obligation may pose a problem.[163]

4. Extent of State-Local Duty.—Exactly what limits exist or may be set on any public duty or undertaking to provide or finance care is not settled by current case law.[164] If a provision is not mandatory, the government can revoke it by ceasing to provide or to finance care.

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[156]*See, e.g.*, Mary Lanning Memorial Hosp. v. Clay County, 170 Neb. 61, 101 N.W.2d 510 (1960).

[157]*See, e.g.*, IND. CODE §§ 12-2-1-1 through -39 (1982 & Supp. 1986) ("Township trustee must promptly provide medical and surgical attendance for all the poor . . . not . . . in public institutions.").

[158]Industrial Comm'n v. Navajo County, 64 Ariz. 172, 167 P.2d 113 (1946); *see also* Memorial Hosp. v. Maricopa County, 415 U.S. 250, 252 (1974) (notes "mandatory" duty of counties).

[159]*See, e.g.*, F. GRAD, *supra* note 134.

[160]*See, e.g.*, ILL ANN. STAT. ch. 34, para. 5011-5029 (Supp. 1986) (Cook County is obligated to finance care for poor).

[161]Calculated from Butler, *supra* note 136, at 17, Table I. *See also* STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93.

[162]N.C. GEN. STAT. § 131E-13 (Supp. 1985).

[163]Andrulis, *Survival Strategies for Public Hospitals*, BUS. & HEALTH, June 1986, at 31, 34.

[164]Interestingly, most cases are brought not by the poor themselves but by hospitals that have provided care to indigents and are requesting compensation for that care.

Courts generally will not obligate a government to undertake a function that is permissive rather than mandatory.[165]

Occasionally, a state or county may operate an indigent health care program simply by appropriating funds without a statutory mandate or even express statutory authority. When such appropriated funds are exhausted, the state or local agency would seem to have no lingering obligation to continue covering care for the indigent.[166]

Where specific statutory language governs indigent care, budgetary discretion may be more circumscribed. Programs vary widely in the discretion granted to control the scope of support through eligibility, benefits, and payment provisions. For example, Iowa gives its county boards of social services broad control over the form and amount of support.[167] California also gives broad discretion to its county supervisors to determine eligibility for, amount of, and conditions attached to indigent relief.[168] However, a county's exercise of discretion must remain consistent with the language and purpose of California's General Assistance statutes.[169] Other states have given local authorities much less discretion. For example, Michigan's GA-medical program sets very precise standards and fixes the local share of resultant spending.[170] Even when counties are given broad administrative discretion, state courts have held that county regulations must bear a reasonable relationship to the intended purpose of the state statute.

A county's obligation to deliver indigent health care does not necessarily change if the state establishes an additional program, such as Medicaid.[171] Similarly, establishing a public medical facility within the county does not necessarily relieve the county's responsibility for indigent care rendered elsewhere. The Nevada Supreme Court, for example, held a county responsible for emergency care rendered at a private hospital even though the county operated its own facility.[172] In contrast, California courts have held that counties were responsible only for care given at

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[165]*See, e.g.*, Perth Amboy Gen. Hosp. v. Board of Chosen Freeholders, 158 N.J. Super. 556, 386 A.2d 900 (1978) (statute which *authorized* counties to make payments to hospitals providing care to indigents did not *require* counties to do so).

[166]*See generally* Butler, *supra* note 136, at 18.

[167]Collins v. Hoke, 705 F.2d 959 (8th Cir. 1983).

[168]City & County of San Francisco v. Superior Court, 57 Cal. App. 3d 44, 47, 128 Cal. Rptr. 712, 714 (1976).

[169]Bay Gen. Community Hosp. v. County of San Diego, 156 Cal. App. 3d 944, 203 Cal. Rptr. 184 (1984); Patten v. San Diego County, 106 Cal. App. 2d 467, 235 P.2d 217 (1951).

[170]MICH. COMP. LAWS ANN. § 400.66a (West 1976); *see* IHPP, *supra* note 136, at 171-74.

[171]Madera Community Hosp. v. County of Madera, 155 Cal. App. 3d 136, 201 Cal. Rptr. 768 (1984); Hall v. County of Hillsborough, 122 N.H. 448, 445 A.2d 1125 (1982).

[172]Washoe County v. Wittenberg, 100 Nev. 143, 676 P.2d 808 (1984).

a county facility or by a provider already under contract with the county.[173]

5. Funding Limitations and Obligations.—The state of Washington statutorily limits public obligations to the appropriated amounts,[174] whereas Ohio positively obligates the county to appropriate needed funds.[175] Some states have given counties specific authority to levy taxes in order to care for the indigent. Idaho, for example, allows counties to levy an ad valorem tax on property.[176] Nevada allows indigent health spending to raise county property taxes above an otherwise binding ceiling percentage on assessments.[177] A public hospital or clinic or a private contractor may simply reach the limit of its resources and then shut down certain services or turn away certain people (or postpone serving them). Presumably, in so doing, it would use accepted principles of medical triage, serving the medically neediest first. Whether a disappointed patient or the provider can then sue the responsible jurisdiction(s) for more than the budgeted funds is not clear.[178] Presumably, a great deal would turn on the precise statutory wording of the institution's duty and the extent of discretion authorized.

6. Specific Terms of Assistance.—Any program of medical assistance requires some operating definitions as to (a) eligible recipients, (b) benefits available (including which providers and what services are covered), and (c) payment levels. As for other aspects of program administration, local administrators generally are given broad discretion, although courts have sometimes limited the exercise of this discretion.[179] For example, a New Jersey court held that a municipality must conform to statewide rules and regulations of public assistance.[180] In a case from

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[173]*Bay Gen. Community Hosp.*, 156 Cal. App. 3d 944, 203 Cal. Rptr. 184; Union of Am. Physicians & Dentists v. County of Santa Clara, 149 Cal. App. 3d 45, 196 Cal. Rptr. 602 (1983).

[174]WASH. REV. CODE ANN. § 74.09.035 (Supp. 1987); *see also* GA. CODE ANN. § 31-8-36(b) (1985).

[175]St. Thomas Hosp. v. Schmidt, 62 Ohio St. 2d 439, 406 N.E.2d 819 (1980); OHIO REV. CODE ANN. § 5101.161 (Anderson Supp. 1985).

[176]IDAHO CODE § 31-3503 (1983); *see also* Idaho Falls Consol. Hosp. Inc. v. Bingham County Bd. of County Comm'rs, 102 Idaho 838, 642 P.2d 553 (Idaho 1982).

[177]NEV. REV. STAT. § 428.050 (1985).

[178]Some courts have held that counties may not be liable for indigent health care beyond their budgets. *See, e.g.*, Board of Directors of Memorial Gen. Hosp. v. County Indigent Hosp. Claims Bd., 77 N.M. 475, 423 P.2d 994 (N.M. 1967); Board of Comm'rs v. Ming, 195 Okla. 234, 156 P.2d 820 (1945); Cache Valley Gen. Hosp. v. Cache County, 92 Utah 279, 67 P.2d 639 (1937). Other courts have held that obligations must be met even if they exceed the county's budget limitations. City & County of San Francisco v. Superior Court, 57 Cal. App. 3d 44, 128 Cal. Rptr. 712 (1976); Hall v. County of Hillsborough, 122 N.H. 448, 445 A.2d 1125 (1982).

[179]*See supra* text accompanying notes 167-70.

[180]Ricker v. Lawson, 155 N.J. Super. 536, 382 A.2d 1183 (1977).

New Hampshire, a United States district court held that a town must administer its assistance program pursuant to written, objective, and ascertainable standards.[181]

To determine eligibility, administrators of indigent health care must define "indigent." The majority of states do not provide a definition within the statute itself, although some statutes include a very general definition. For example, New Hampshire defines those who are entitled to free health care as those who are "poor" and unable to support themselves.[182] Idaho defines the medically indigent as "persons needing hospital care without income or resources sufficient to pay for necessary medical care."[183] Some states have included within their statutes more precise definitions of "indigent." Arizona, for example, establishes specific income and resource standards.[184] Oklahoma defines an indigent as a person with income under the federal poverty level, with resources insufficient for self care, and with a need for hospital care.[185]

Where statutes have provided no definition of indigency or only a general definition, state courts have often played an active role in interpreting the statute. The Supreme Court of Montana, for example, held that the counties must have flexible eligibility standards that take into consideration not only income but also family debts and outstanding medical bills.[186]

In defining indigency, most state statutes contain residency or citizenship requirements. However, in 1974, the United States Supreme Court held that an Arizona statute requiring a year's residence in a county as a condition of indigent care was unconstitutional under the equal protection clause.[187] Since this ruling, several state courts have invalidated other similar durational residency requirements. More recent statutes simply require the indigent to be domiciled in the state with an intent to reside there.[188] This type of residency requirement would seem to answer the equal protection concerns stated by the Supreme Court.[189]

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[181]Baker-Chaput v. Cammet, 406 F. Supp. 1134 (D.N.H. 1976).

[182]N.H. REV. STAT. ANN. § 165:1 (Supp. 1986).

[183]IDAHO CODE § 31-3503 (1983).

[184]ARIZ. REV. STAT. ANN. § 36-2905 (Supp. 1986).

[185]OKLA. STAT. ANN. tit. 56, § 58 (West Supp. 1987).

[186]Saint Patrick Hosp. v. Powell County, 156 Mont. 153, 477 P.2d 340 (1970); *see also* Hall v. County of Hillsborough, 122 N.H. 448, 445 A.2d 1125 (1982); Sioux Valley Hosp. Ass'n v. Davison County, 319 N.W.2d 490 (S.D. 1982).

[187]Memorial Hosp. v. Maricopa County, 415 U.S. 250 (1974).

[188]*See, e.g.*, MONT. CODE ANN. § 53-3-315 (1985).

[189]In 1982, the United States Supreme Court held unconstitutional a Texas statute which prohibited illegal aliens from enrolling in public schools. Plyler v. Doe, 457 U.S. 202 (1982). This case would seem to indicate that states could not deny indigent health care to undocumented aliens. However, language in the opinion can be interpreted as limiting the holding to educational rights of minor children.

States have differed in their treatment of undocumented aliens. The New Mexico Supreme Court held undocumented aliens were "residents" for purposes of the indigent care statute.[190] However, a California court recently held that counties were not required to reimburse private hospitals for care of undocumented aliens because the statute required indigents to be "lawful" residents.[191]

Most state statutes do not specify which providers or what services are covered under their indigent health care laws.[192] Thus, the counties often have considerable discretion in determining the type of care covered and who may be paid as providers. Although state courts generally have upheld this broad discretion, California courts have held that a county has no obligation to pay for indigent care delivered at a facility other than its own or one with which it has contracted.[193] In contrast, the Idaho Supreme Court required an Idaho county to pay a hospital that was neither under contract nor even within the state.[194] (The case involved an Idaho resident's going to nearby Salt Lake City, a logical and common pattern; query whether more distant hospitals would be paid.) Even those states that require a contractual relationship with the provider often allow recovery by noncontractors in emergency situations.[195]

The particular services covered by indigent health care programs also vary widely from state to state.[196] Most state indigent statutes cover at least emergency care. Some states cover a broader range of health care needs. Arizona, for example, provides for hospitalization and medical care, including long-term care and home health services.[197]

Judicial interpretations of coverage provisions have been important. The Indiana courts, for example, have construed an Indiana provision that covers indigents suffering from a "disease, defect, or deformity" to exclude normal pregnancy.[198] In a later case interpreting the same

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[190]Perez v. Health & Social Servs., 91 N.M. 334, 573 P.2d 689 (1977).

[191]Bay Gen. Community Hosp. v. County of San Diego, 156 Cal. App. 3d 944, 203 Cal. Rptr. 184 (1984).

[192]*See, e.g.*, CAL. WELF. & INST. CODE § 17000 (West 1980); CAL. GOV'T CODE § 29606 (West 1968). California's statute directs counties to "relieve and support" the incompetent, poor and indigent, and "necessary expenses" incurred in this support are charged to the county. *See also* NEB. REV. STAT. § 68-104 (1984). Nebraska's statute directs counties to provide "medical and hospital care" to "the poor".

[193]*E.g.*, *Bay Gen. Community Hosp.* 156 Cal. App. 3d 944, 203 Cal Rptr. 184.

[194]University of Utah Hosp. & Medical Center v. Bethke, 101 Idaho 245, 611 P.2d 1030 (1980).

[195]County Dep't of Public Welfare v. Trustees of Indiana Univ., 145 Ind. App. 392, 251 N.E.2d 456 (1969); Washoe County v. Wittenberg, 100 Nev. 143, 676 P.2d 808 (1984).

[196]*See generally* IHPP, *supra* note 136, at 67-292 (state-by-state profiles).

[197]ARIZ. REV. STAT. ANN. § 11-291 (Supp. 1986).

[198]Lutheran Hosp. of Fort Wayne, Inc. v. Department of Public Welfare, 397 N.E.2d 638 (Ind. Ct. App. 1979) (construing IND. CODE § 12-5-1-1 (1982)).

statute, an Indiana court held that a county may not restrict the number of inpatient days.[199]

Few indigent care programs set the type of particularized limits or conditions on services that have become common in conventional private group health insurance and in Medicaid, such as pre-admission screening for nonemergency hospital admissions.[200] Indigent programs that are integrated with Medicaid present an exception.[201] Thus, the validity of controls of this kind seems not to have been litigated.

Program specifications, or the lack thereof, also govern payment levels, an important indirect influence on access to care. Medicaid-integrated programs generally pay Medicaid rates, and contractual providers receive the contracted-for amounts. Many older-style indigent vendor-payment programs, however, pay hospitals flat, per-day amounts.[202] Two older state statutes oddly prohibit price setting through bids[203]—quite contrary to recent innovations in practice, notably in Arizona and California.[204] One early Nebraska case disqualified counties' prepayment for services as "insurance,"[205] but this holding seems obsolete in light of recent trends toward prepayment in Medicare and Medicaid.

Most states or counties have established varied procedural requirements that providers or patients must follow to receive payment for indigent health care. Many states require prior governmental approval or a contractual agreement before a provider renders care to an indigent. However, this requirement may be waived in emergency situations.[206]

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[199]Welborn Memorial Baptist Hosp., Inc. v. County Dep't of Public Welfare, 442 N.E.2d 372 (Ind. Ct. App. 1982).

[200]*See, e.g.*, J. CALIFANO, *supra* note 22; P. FOX, W. GOLDBECK & J. SPIES, *supra* note 22; J. HOLAHAN & J. COHEN, *supra* note 18.

[201]Maryland, for example, simply includes indigents not eligible for federal Medicaid assistance within the same state-federal Medicaid program, but wholly at state expense. *See* IHPP, *supra* note 136, at 157-59.

[202]*See, e.g.*, Massachusetts Gen. Hosp. v. Cambridge, 347 Mass. 519, 198 N.E.2d 889 (1964) (hospital rate for voluntarily treated indigents is purely statutory and can be below actual incurred expenses); DEL. CODE ANN. tit. 29, § 7204 (1983); *see also* Springfield Hosp. v. Comm'r of Public Welfare, 350 Mass. 704, 216 N.E.2d 440 (1966) (hospital rate for old age assistance patient below actual cost is valid; hospitals are "greatly affected with the public interest" and have a "civic obligation" to serve patients).

[203]CONN. GEN. STAT. ANN. § 17-274 (West Supp. 1986); UTAH CODE ANN. § 17-5-55 (Supp. 1986).

[204]*See, e.g.*, J. CHRISTIANSON & D. HILLMAN, HEALTH CARE FOR THE INDIGENT AND COMPETITIVE CONTRACTS: THE ARIZONA EXPERIENCE (1986); L. JOHNS, R. SERZAN & M. ANDERSON, SELECTIVE CONTRACTING FOR HEALTH SERVICES IN CALIFORNIA, FINAL REPORT (1985).

[205]Hustead v. Richardson County, 104 Neb. 27, 175 N.W. 648 (1949) (counties not authorized to engage in business of insurance).

[206]University of Utah Hosp. & Medical Center v. Bethke, 101 Idaho 245, 611 P.2d 1030 (1980).

D. Obligations of Private Health Insurers

Would-be insureds have no general legal right to private health coverage, and there is little tradition of providing free or below-cost insurance as there has long been for providing hospital care. Insurance is a private contract, only partially regulated, available to those who can afford it and not to others. Several qualifications to this "no rights" generalization deserve mention.

First, if workers or their dependents are covered through a workplace group and they cease to be group members, because of layoff or widowhood, for example, they are entitled to continue on the group policy at their own expense for a certain period.[207]

Second, in most states, Blue Cross/Blue Shield plans in theory must allow open enrollment in their nongroup plans.[208] This is one regulatory stricture that can be seen as a public quid pro quo for granting the Blues tax exemption. Moreover, such nongroup Blues rates may be kept low by direct or indirect subsidy from the Blues' group business if their group market share is strong enough to permit this;[209] they also often use a version of "community rating" principles. Community rating charges all insureds in a large pool the same price (based on the pool's average cost), rather than basing rates on the specific experience of subgroups. Pooling experience arguably helps the poorest and sickest, whose experience is the worst, at the expense of lower-risk insureds.[210]

Finally, ten states now guarantee otherwise uninsurable people the right to conventional insurance at a subsidized rate.[211] Coverage is rea-

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[207]This "continuation" privilege (or the ability to "convert" to a relatively generous individual policy) arose first through industry custom, then through state and federal law. On custom, see HEALTH INS. ASS'N OF AM., GROUP HEALTH INSURANCE 1-17 (1976); for state rules as of Spring 1985, see IHPP, *supra* note 136, at 294-95; for new federal rules from COBRA legislation, extending the right to coverage to a period up to three years in some cases, see Bovbjerg, *supra* note 24, at 405-06 nn. 12 & 13.

[208]*See, e.g.*, IND. CODE § 27-8-11-3 (Supp. 1986). It is thought that in recent years, the Blues' commitment to open enrollment has waned under competitive pressure. *Cf.* U.S. GEN. ACCT. OFF., PUB. NO. HRD-86-110, HEALTH INSURANCE: COMPARING BLUE CROSS AND BLUE SHIELD PLANS WITH COMMERCIAL INSURERS (July 1986) (Blues' differences from commercials described as minor).

[209]In Massachusetts, for example, by order of the Insurance Commissioner, one percent of group premiums helps defray nongroup expenses. Indirect subsidies may be achieved by regulatory accounting rules that attribute the same administrative loading factor to group coverage as to nongroup, when in fact group practice could normally be expected to achieve economies of scale in sales and operations. *Cf.* Bovbjerg, *supra* note 24, at 409.

[210]Under competition from more experience-rated policies, largely in the group market, community rating pools tend to fragment, as low-risk groups insure on their own rather than remain in the community pool. For a description of how such competition ended early community rating in the group market, see P. STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 329-31 (1982).

[211]In one of the ten, Connecticut, the pool is not restricted to persons rejected by conventional insurers. *See* Bovbjerg & Koller, *State Health Insurance Pools: Current*

sonably generous by non-group standards, but enrollments are very low, even as a fraction of the tiny percentage of uninsurables.[212] Even with considerable subsidy, policies cost 150% or more of the price of standard coverage.

These various insurance rules all help would-be insureds, but do require them to pay for their own coverage, albeit at relatively favorable rates. Thus, they probably do not reach many or most of the medically indigent, who are relatively poor or unemployed or both. They may, however, help prevent medical indigency among the nonpoor caused by large medical bills that exceed ability to pay.

One common type of state insurance regulation tends to make insurance relatively less affordable, namely "mandatory benefits" rules that require all health insurance policies to cover certain services, notably mental health care. Mandated benefits "upgrade" insurance protection for those who can afford it, but disproportionately burden poorer insureds and their employers and tend to make it more difficult for those less able to pay to buy any coverage at all.[213]

IV. Private and Public Approaches Toward Improvement

A. Introduction: Where We Stand

The problems of the uninsured and of the uncompensated care they generate are increasing. Legally, there is tenuous support for a right to care or coverage in the constitutional or statutory sense, as just noted. Most of the obligations are conditional: that is, if a provider, an insurer, or the government assumes to provide care or coverage for someone, then it must provide care or coverage of a certain standard. In any event, this branch of the law appears to be poorly developed in terms of the jurisprudence of rights. Indeed, for the most part, cases on indigent coverage do not even cite one another. As a result, the body of case law provides little guidance.

Performance, Future Prospects, 23 Inquiry 111 (1986) (experience of six pools operating before 1984). The states are Connecticut, Florida, Indiana, Iowa, Minnesota, Montana, Nebraska, Ohio, Rhode Island, Tennessee, and Wisconsin. As of late 1986, ten states now have risk pool legislation, according to the National Governors' Association. G. Claxton, Concept Paper: Facilitating Health Care Coverage for the Working Uninsured 14 (Nat'l Governor's Ass'n, Pre-Conference Draft, Dec. 1986).

[212]Bovbjerg & Koller, *supra* note 211. About one percent of the population is thought to be uninsurable. *Id. See also supra* note 26 and accompanying text.

[213]*See* Demkovich, *supra* note 50. Such rules disproportionately burden small group and nongroup coverage because large workplace groups very often "self-insure" precisely so as to escape such state insurance mandates and achieve other economies. *See* Bovbjerg, *supra* note 24, at 408. Over half of large employment groups are now thought to self-insure. *See infra* note 273.

Any effective solution will require at least some government involvement, although the nature of that involvement may vary considerably according to circumstances. Past political responses to the problems of the poor have varied enormously, and there is considerable disagreement about the approach that should be taken.

B. Private Sector Approaches

"Leave it to the private sector" is the understandable response of many people to medical indigency. After all, most of the progress in past generations was due to the astonishing success of private group health coverage. It is largely responsible for bringing health coverage to approximately ninety percent of American workers and their dependents.[214] Moreover, "mainstream" employment group coverage prepays for most typical medical and dental services from almost any licensed provider at little out-of-pocket cost to the insured—thus guaranteeing access to care while also protecting against poverty-inducing catastrophe.[215]

The spread of workplace group insurance, however, seems to be reaching its natural limit.[216] Under current economic conditions, it appears that a relatively high level of "structural uninsurance" will remain. Of course, this level will vary from place to place depending upon economic conditions, the employment structure of the economy, existing tax incentives, and so on.

Relying on private efforts to increase insurance can only partly address the problem of medical indigency. Private coverage can reach only those with the wherewithal to pay for coverage. It thus bypasses the indigent, although more coverage would tend to prevent the type of medical-financial catastrophe that can cause people to become medically indigent.

Most employed people who do not have "proper" coverage and who might expect to benefit from private solutions are in small employment groups. Of employees in larger groups (100 or more employees), nearly 100% have coverage, whereas fewer than half of the people in smaller employment groups have health coverage.[217] The plain fact is that existing forms of coverage sold through existing organizational arrangements simply cost more than many of these workers and their

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[214]*See, e.g.*, Moyer & Cahill, *supra* note 24; *see also supra* notes 12-15 and accompanying text.

[215]Medicare and Medicaid are similar to private coverage in this regard; they have essentially adopted the workplace model of middle class style coverage for their particular populations.

[216]*See supra* text accompanying notes 46-52.

[217]*See, e.g.*, Moyer & Cahill, *supra* note 24. The problem is thought to be still worse for very small groups, those with twenty, ten, or fewer employees.

employers are willing to pay. For smaller, poorer workplaces and for individuals, covering the same medical expenses costs more per capita in absolute terms, costs much more as a relative share of earnings, and receives considerably less government "subsidy" in forgone taxes.[218]

For large groups, medical experience is more predictable (and hence more insurable), and economies of scale make coverage cheaper to sell and to administer. Relative costs of sales, administration, claims settlement, and regulation all rise as group size declines; and many of the economizing methods of large groups are not available to smaller ones, at least not to the same degree—including, for instance, self-insurance, sophisticated protocols for screening and reviewing care, and negotiating favorable rates with medical providers. Smaller groups can combine into larger ones, but artificially created large groups do not act like naturally existing groups.[219] Finally, the tax-free status of workplace health benefits provides a greater benefit to higher income workers than to poorer ones because income taxes are progressive. Those working poor most in need of assistance pay no income tax at all but likewise receive no tax benefit from buying medical care through workplace coverage, unlike their middle class counterparts.

Some private initiatives offer opportunity for improvement, notably in underwriting and pooling smaller groups and in developing attractive plans with better cost-containment features.[220] Attitudes about the importance of insurance may also change. However, substantial changes in the extent of purely private coverage look implausible in the near future. Clearly, more fundamental changes will require more government involvement, either through direct or indirect subsidies or through some form of mandates or coercion. Again, this should not be surprising. If the poor and near poor cannot or do not cover themselves voluntarily, someone else must pay for their care, at least in part.

C. Public Sector Approaches

Any model of coverage and care for the medically indigent must address four basic questions: who should be eligible; what should be the nature of the product or program; how should it be financed; and how should it be administered.[221] This Article next examines a number

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[218]On the problems of small versus large groups in insurance markets, see Bovbjerg, *supra* note 24.

[219]Differences stem mainly from adverse selection, increased sales and administrative expenses, and instability over time. *See generally id.*

[220]*Id.*

[221]There are many ways to characterize options for indigent coverage and care, and each author tends to develop his own. These four issues cover the fundamental choices. For somewhat different categorizations, see, e.g., IHPP, *supra* note 136; STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93; Bartlett, *Overview of Public Policy Options*

of models and the different ways they attempt to answer these questions.

1. Eligibility for Assistance.—The uncertain nature of medical indigency makes it difficult to determine who should be eligible. One problem is the difficulty of deciding what constitutes "need." Taxpayers and the political systems that represent them are unwilling to finance unlimited amounts of everything called "medical care" for all those who cannot or do not provide for themselves. From a policy perspective, it is clearly inappropriate to undercut incentives for self-help and to promote "free riding" by many people who would normally insure themselves but who would happily take free public assistance instead.

Another problem with defining eligibility in advance is that relevant circumstances are not fixed: employment status changes, and people's incomes go up and down, as does their medical spending. The inability to foresee such changes complicates the operation of an insurance-style program, which contemplates coverage for a defined population over a preset time period. The uninsured, in notable contrast, are a constantly shifting and unstable grouping.

Nonetheless, some eligibility guidelines must be created, using income, assets, medical status, and other characteristics of potential eligibles. One way to deal with shifting circumstances is to allow administrators discretion to reevaluate eligibility on a continuous basis (for each hospital admission, for example). A major *legal* question is to what extent administrators will be allowed discretion to grant or deny eligibility for unusual circumstances; indeed, existing medical indigency programs often have extremely vague standards. These standards could be difficult to sustain against an attack on due process grounds.[222] A major *practical* concern is that constant reconsideration is not only expensive for public administrators but also a deterrent to private actors who may be at risk as a result of a finding of non-eligibility. Vagueness makes it difficult for both eligibles and providers who deal with them to know where they stand; this uncertainty must hurt access to care for these uncertain eligibles.

At any given level of public spending, there is a clear trade-off between covering more people and providing more benefits: the more people covered, the higher the expense. Indeed, of any design decision, eligibility has the greatest impact on total program spending. The quickest way to increase or decrease spending is to add to or subtract someone

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to Improve Access for the Medically Indigent, in ACADEMY, *supra* note 136, at 47; Butler, *supra* note 136; Hughes, *Local Anesthetics: A Look at States' Programs for the Uninsured,* HEALTH/PAC BULLETIN, November 1986, at 11; Lewin & Lewin, *Health Care for the Uninsured*, BUS. & HEALTH, September 1984, at 9; Wilensky, *Underwriting the Uninsured: Targeting Providers or Individuals,* in UNCOMPENSATED HOSPITAL CARE, *supra* note 30, at 148.

[222] *See* Butler, *supra* note 136; STATE AND LOCAL GOVERNMENT RESPONSIBILITIES, *supra* note 93, at 19-22.

from the rolls. Other program adjustments have a much smaller fiscal impact than completely dropping or adding an additional person.

One way to avoid having to make an all-or-nothing eligibility decision is to require people to contribute something on their own on an income-related basis, even if they receive public assistance. Public assistance then subsidizes self-help rather than wholly replacing it. This can be done in advance by making beneficiaries share in premium payments, or after the fact, by making them co-pay for incurred medical expenses. Nevertheless, requiring even partial payments from poor people in need of care is distasteful to many; cost sharing under Medicaid has met with considerable political reluctance.[223] Moreover, it has often proven difficult for providers to be very vigorous or effective in collecting their unpaid share of bills from a relatively poor population.

Another possibility is to target specific groups seen as fiscally or medically needier than others or those for whom the public investment in care is perceived to have the largest benefit. The most obvious group on both these counts is composed of low-income children and expectant and recently delivered mothers. Numerous states are beginning to target Medicaid expansions in this manner; the same could hold true for other public efforts to aid the indigent.[224]

Of course, setting eligibility standards to aid the medically indigent is more easily described in the abstract, as here, than actually implemented. As already noted, the concept of medical indigency is itself not easy to define.[225] Numerous programmatic problems arise in defining what support to provide to people at what levels of income and assets: For example, over what period of time is income measured? What assets count, including those of family members, and how are they to be valued? What "spend down" of income or assets (to meet large, uncovered medical bills) makes an otherwise non-indigent person eligible?[226] Once an operational definition of medical indigency is created, including

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[223]Traditionally, Medicaid programs have not been allowed to charge co-payments, although this has changed somewhat of late. *See Cost Sharing by Recipients,* 3 Medicare & Medicaid Guide (CCH) ¶ 14,731 (March 1983).

[224]*See, e.g.*, Dallek, *States Study Health Care for the Uninsured Poor*, 18 Clearinghouse Rev. 740, 743 (1984); Kosterlitz, *Concern About Children*, Nat'l J., Sept. 20, 1986, at 2255 (state task forces have recommended special attention to children in Colorado and Texas, for example). Recent federal legislation has allowed expanded coverage. *See infra* note 237.

[225]*See supra* note 9.

[226]Medicaid has of course had to create numerous rules and administrative mechanisms to decide eligibility; eligibility is generally conceded to be the most complex and difficult part of Medicaid to describe or understand. *See, e.g.*, Joe, Meltzer & Yu, *Arbitrary Access to Care: The Case for Reforming Medicaid*, Health Aff., Spring 1985, at 59. Complexities make it difficult even to know how many people are eligible for any Medicaid program at a particular time; hence reliable program statistics focus on the number of known "recipients" of covered care. *See, e.g.*, J. Holahan & J. Cohen, *supra* note 18, at 45.

of necessity lack of adequate health insurance, it becomes difficult to avoid "free riding" by eligible beneficiaries who, absent public aid, would cover themselves through their own or their employers' efforts. Even many low-income people have some insurance. Various strategies exist to address this problem, but none is perfect.[227]

2. The Product: Hospital Payment vs. Insurance.—What is to be provided to those who are eligible? Should public aid focus only on hospital services, or should it instead provide for broader availability of medical services, typically through an insurance-like mechanism? Either approach can use public or private hospitals or insurance plans.

a. Hospital-based programs.—Three basic program models focus on hospitals. The first is to operate a public hospital or, increasingly, to contract with a private entity to operate it. Under the public hospital model, the hospital not only provides services but also determines eligibility and benefits, since it is typically left to the hospital to decide whom to serve, in what order, and how much care to give. It can be difficult to establish good public budgetary control over these hospital choices. Public hospitals have been an important source of care for the medically indigent, but the trend is toward reducing rather than increasing the public role in this area.[228]

A second possibility is to contract with a number of hospitals, public and private, for the delivery of particular care to a particular population. This model is often followed for small, specific public health programs,[229] but is less often used for general medical care for the medically indigent.[230] Its use could be expanded. A major advantage of contracting over the public hospital approach is that it may provide some competition among hospitals for the contract(s). In any event, in many areas there is no public hospital, and the contract approach offers a simple way to pay for care.

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[227]Eligibility standards can be set very stringently to cover only the desperately poor, who can seldom contribute to their own coverage in any case. But this eliminates the working poor, with some income, who contribute large numbers of uninsured. A "sliding scale" of income-related assistance is a promising alternative, but requires ongoing administrative complexity either to bill beneficiaries for their share of public premiums or to give them "vouchers" to buy private coverage. Another mechanism is to offer assistance to only the "hard core" uninsured, for example, by requiring that beneficiaries have gone two years without any private coverage. This discourages free riding but again leaves uncovered many otherwise deserving potential eligibles. Requiring "maintenance of effort" in terms of employers' buying private insurance is another possibility, but is administratively complex: monitoring and enforcement for hundreds of thousands of small workplaces would be needed, more if individual self-help were required.

[228]*See supra* notes 57, 58, 142 & 143 and accompanying text.

[229]*See supra* note 145 and accompanying text.

[230]An exception is Iowa where, with state funds, the University of Iowa Hospital and Clinics provide "free" care to all county-certified indigents (up to a preset quota) from all over the state. *See* IHPP, *supra* note 136, at 139.

A third model, already in use in many states, is to cover a group of qualifying hospitals under a "vendor payment" program.[231] Under this model, eligibility standards may be defined by the program, with hospitals put at risk to obtain verification of patients' eligibility before delivering nonemergency services.

These options have been aggregated under the rubric of hospital-based approach because by far the bulk of such programs' spending normally goes to hospitals. A limited amount of non-hospital outpatient care could also be provided through direct dealings with non-hospital providers, primarily those affiliated with public health systems. Public health systems provide various primary, preventive, and other medical services through public health clinics operated by local governments and staffed with public health nurses, doctors, and others.[232]

The major advantage of the hospital-based approach is that it builds on the existing system. After all, hospitals deliver the most crucial care, receive the bulk of current spending on the medically indigent, and provide the most uncompensated care. The other advantage of a hospital-oriented approach is its relative ease of operation and finance. The number of hospitals, especially public hospitals, is relatively small, which facilitates dealing with them. It would be far more difficult to deal on the same basis with physicians or other more numerous providers.

b. Medicaid and lesser "insurance" programs. (i.) Advantages of insurance.—The second basic approach is not hospital-oriented but rather recipient-oriented—in short, insurance or something very much like it. Insurance-style programs cover a broader spectrum of care and determine eligibility not merely for one hospital episode, but for a set period of time, much as private insurance enrolls people for a year or for some other term of coverage.

Paying only for hospital care means covering only the most expensive care and forgoing whatever possibilities exist to treat medical problems before they become sufficiently serious to warrant institutionalization. It also delegates to hospitals considerable control over who is to receive care and to what extent. Moreover, if only public hospitals or a limited number of private hospitals specialize in care to the poor, a hospital-oriented approach also fails to promote quality competition, which may be important in assuring that poor people get adequate care. There is also some danger that any hospitals designated under a hospital-only approach would be at least perceived as being lower quality, welfare-style hospitals and hence would be shunned by the insured middle class.

In contrast, an insurance entitlement empowers the patient rather

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[231] *See, e.g.*, Butler, *supra* note 136, at 19-20; *see supra* text accompanying notes 146 & 147.

[232] *See, e.g.*, ROLE OF STATE AND LOCAL GOVERNMENTS, *supra* note 134; PUBLIC HEALTH FOUNDATION, *supra* note 135.

than the provider.[233] Giving people control over their own insurance money gives them a measure of dignity in contrast to shunting them to a "charity" hospital. It also allows both patients and providers to plan for medical care to a greater extent. Moreover, giving people the resources with which to "shop around" may promote desirable quality competition.

Quality is also enhanced by hospitals' and doctors' serving the medically indigent alongside better funded and possibly more demanding patients. Covering more than hospital services promotes health maintainence and thus avoids some needs for inpatient care. This method may or may not save money overall, but it certainly makes people better off.[234] Finally, under an insurance plan, a partial public subsidy is more feasible because the beneficiaries' share is collected in advance, when they are more likely to be healthy and employed. Collecting at the time of medical need or thereafter, as with the hospital-based plans described above, is more difficult. For all of these reasons, this Article strongly supports insurance-style programs for the medically indigent, to the fullest extent that they are politically and economically feasible.

Economic feasibility is, of course, the Achilles' heel of this insurance approach. Broad coverage can be far more expensive than simply relying on public hospitals, both because the price per unit of service may be higher and because a great deal more care may be delivered and consumed.[235] The great challenge, then, for those who favor an insurance-style approach is to find ways to provide coverage that is less expensive than conventional approaches or to persuade the electorate that expansion of existing programs is fiscally prudent and a good medical value.

(ii.) Options for expanding Medicaid.—The best known and by far the largest insurance-style approach is Medicaid. Indeed, the most straightforward way to expand coverage for the medically indigent would be to cover more poor people under Medicaid. For states, Medicaid is a good insurance "buy" because the federal government pays half or more of program spending on an open-ended basis. Medicaid coverage could be expanded by raising the income standards for eligibility, by choosing to cover people in optional categories such as two-parent families or children aged 18-21 or by operating "medically needy" programs that allow people to "spend down" to eligibility.[236] Additional expansions

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[233]For one view of the importance of empowering patients, see Bovbjerg & Held, *Ethics and Money: The Case of Kidney Dialysis and Transplantation*, TOPICS IN HOSP. L., Sept. 1986, at 55.

[234]It is poorly appreciated that much so-called "preventive" medical care is not cost-effective, that is, does not save a dollar in prevented care for every dollar invested in prevention. *See generally* L. RUSSELL, IS PREVENTION BETTER THAN CURE? (1986).

[235]People without insurance now get much less care even though they are sicker. Giving those people coverage can thus be expected at least to double the amount of care that they get in hospitals and perhaps similarly for outpatient services. *See supra* Table 4 & note 27.

[236]Few states maximize federal financial participation in Medicaid by setting the highest allowable income limits and covering all optional eligibility categories. *See generally* J.

would be possible if federal requirements for categorical eligibility as well as low income were eased.[237] However, the fact that states have not expanded Medicaid eligibility indicates that they think it is too expensive to cover more people in this way—even with federal subsidies.[238] The one major area of program expansion in recent years has been to add coverage for poor children and their mothers.[239] Of course, states are free to cover others as they please, without federal assistance.

(iii.) New economizing options.—If Medicaid and other traditional programs are perceived as too expensive, what alternatives exist? The keys to economizing are to hold down the price and utilization of medical care. This must be accomplished without leaving uncovered large expenses for catastrophic care, a central goal of good coverage. It is especially important to limit expensive hospital care, through some combination of provider and patient incentives, prescreening of admissions, reviews of care given, and judicious substitution of outpatient for inpatient care.

The other critical element is to lower prices paid to providers, particularly hospital payments.[240] From the standpoint of the hospitals,

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HOLAHAN & J. COHEN, *supra* note 18. This is one reason that only about 40% of poor people are Medicaid eligible. *Id.* For a good short review of Medicaid eligibility options, see Reymer, *Medicaid Eligibility Options*, in AFFORDING ACCESS TO QUALITY CARE 1 (R. Curtis & I. Hill eds. 1986).

[237]Recent federal amendments have taken a first step toward easing categorical requirements by allowing coverage of expectant mothers and poor children not receiving AFDC cash assistance. *See* Consolidated Omnibus Budget Reconciliation Act of 1985, PUB. L. No. 99-272, §§ 9501, 9511, 100 Stat. 82, 201, 212; Omnibus Budget and Reconciliation Act of 1986, Pub. L. No. 99-509, 100 Stat. ____; *see also* Kosterlitz, *Breaking Medicaid's Link with AFDC*, NAT'L J., Sept. 20, 1986, at 2256. But more significant expansions seem unlikely. The current administration has sought to *cap* federal Medicaid obligations rather than allowing states to expand them yet further. R. BOVBJERG & J. HOLAHAN, *supra* note 18, at 7-10, and budget deficits make congressional initiative unlikely as well. *See also supra* note 63.

[238]The number of Medicaid recipients has remained stable in the 1980's, despite increased need for coverage. *See supra* notes 18-19 and accompanying text. *See also* J. HOLAHAN & J. COHEN, *supra* note 18, at 40-43.

[239]The 1981 Medicaid amendments gave states the authority to target children's care without having to provide full medically needy benefits for the elderly and disabled, who consume far greater resources for less obvious returns in avoiding other long term medical costs. R. BOVBJERG & J. HOLAHAN, *supra* note 18, at 33-35. In the case of children, it is possible to provide cost-effective care by expanding preventive and prenatal services and thus to avoid many of the very large bills which can accompany difficult deliveries and disabled or crippled children. Subsequent federal changes have both required and allowed more coverage of children. *See supra* note 237.

[240]Of course, a key feature of any such program for the indigent would be a requirement that the provider accept payment from the program as payment in full, except perhaps for specified cost sharing by patients. That is currently done in both Medicare and Medicaid with regard to hospitals. *See Admissions and Quality Review*, 1 Medicare & Medicaid Guide (CCH) ¶ 4227 (Nov. 1984); and *Reimbursement in General*, 3 Medicare & Medicaid Guide (CCH) ¶ 14,723 (Oct. 1984) (Medicare); *Limitations on Charges to Beneficiaries*, 3 Medicare & Medicaid Guide (CCH) ¶ 20,883Q (Oct. 1985); and *Acceptance of State Payment as Payment in Full*, 4 Medicare & Medicaid Guide (CCH) ¶ 21,833 (June 1985) (Medicaid).

this may not be disadvantageous if it helps reduce the total amount of uncompensated care and increase the number of paying patients. Of course, one must take care not to reduce payments so far as to deny beneficiaries desired access to care.[241] Prices can be held down either by setting prices administratively for public programs, by regulating prices of providers, or by using bidding or negotiation to select providers who are willing and able to accept lower prices for a higher volume of patients.[242] Benefits redesign—better targeting of benefits to needs—may also be helpful; the optimal mix of benefits is probably not provided in the traditional insurance policy.[243]

What new arrangements embody these principles? Perhaps the best known example is the Health Maintenance Organization (HMO). HMO's use restricted panels of physicians and hospitals to deliver care and are thought to be less costly than conventionally provided insurance on a fee-for-service basis with open access to all providers of the patient's choice.[244] Many state Medicaid programs now promote HMO's for their eligible participants; programs in California and Michigan have long advocated this approach.[245] Unfortunately, HMO's do not exist in all parts of the country.

Using HMO's to care for the medically indigent presents other problems as well. First, existing HMO's would want to be prepaid on a monthly basis and guaranteed enrollment for six months or more, as is possible under Medicaid.[246] However, the medically indigent can be a floating population; some are transient, others are only intermittently uncovered by private insurance or Medicaid. Second, HMO's are geared to provide comprehensive, high quality care at a price not unlike that charged by private conventional insurance. As a result, HMO's cost considerably more per capita than what a state might pay for a public hospital or for a limited vendor payment program.

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[241]The same holds true for physicians: It is desirable not to overpay physicians, but if physicians are underpaid, they will not provide enough of the services needed to keep people healthy and out of hospitals. This has been an endemic problem for states' Medicaid programs. Low physician payment often results in people going to hospital emergency rooms or outpatient departments for primary care that would have been much more cheaply provided in physicians' offices. *See generally* J. HOLAHAN & J. COHEN, *supra* note 18, at 62.

[242]*See generally* Bovbjerg, Held & Pauly, *supra* note 58; *infra* text accompanying notes 253-56.

[243]Long distance transportation (e.g., to less expensive outlying institutions) or non-traditional providers for chronic-care services are two services not conventionally covered but which could be cost-effective if implemented on a controlled basis.

[244]The extent of HMO savings has long been debated. It is clear that people in HMO's use significantly less hospital care than others. H. LUFT, HEALTH MAINTENANCE ORGANIZATIONS: DIMENSIONS OF PERFORMANCE (1981). It is not clear to what extent this is due to HMO economies rather than to self-selection by enrollees.

[245]R. BOVBJERG & J. HOLAHAN, *supra* note 18, at 57.

[246]*Id.* at 58.

Another possibility is the so-called Preferred Provider Organization (PPO).[247] Using existing hospitals and doctor practices, PPO's operate like a cross between conventional insurance, covering all providers, and HMO's, with a limited list of covered providers. PPO's encourage enrollees to use one of a selected group of so-called preferred providers, who have agreed to hold down spending either by discounting their normal fees or by agreeing to utilization reviews or other cost-containment measures.

PPO beneficiaries have fewer cost sharing requirements for using preferred providers than for using other providers, who are still covered but at a lower rate. Both beneficiaries and preferred providers profit from this approach. Beneficiaries receive full benefits from a restricted list of providers, yet retain the ability to go to anyone at some additional expense. Preferred providers benefit, despite lower fees or restrictions, because they can expect to receive additional patients from the PPO or at least to retain patients they might otherwise have lost. Since their inception in the early 1980's,[248] PPO's have grown rapidly, but have only recently expanded their marketing to include small groups and individuals. It is not known whether any states or localities have attempted to contract with private PPO's to enroll the medically indigent. As with HMO's, PPO's currently compete primarily in the employment group market and provide relatively complete benefit packages and high quality care.

Another cost containment approach, which can be used in conjunction with either conventional insurance or alternative systems like HMO's and PPO's, involves "managed care." Management means increased control over care by physician or nonphysician reviewers. One common approach is "case management" by a primary care physician, an internist, or a family physician. These physicians act as the patient's point of entry for all care, controlling referrals to specialists and hospitals and often reviewing the latters' care and charges. Traditional medical practice has long been conceived as similarly beginning with a primary care provider who then makes appropriate referrals, but in practice, many patients have gone directly to high-priced specialists or hospital care on their own. Moreover, even transfers from primary care physicians have not normally involved fiscal management, although some medical follow-up may exist. In contrast, case managers act like true "gatekeepers" by controlling access to and use of care on both economic and medical grounds. Various models exist, not all of which have been successful.[249]

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[247] *See, e.g.*, Gabel & Ermann, *Preferred Provider Organizations: Performance, Problems, and Promise*, HEALTH AFF., Spring 1985, at 24.

[248] *See* Bovbjerg, *supra* note 24.

[249] It is possible, for example, to put financial risk on managing physicians, or merely to reward them for being parsimonious in their patients' use of medical resources.

A number of areas are experimenting with case management as a way of holding down medical costs while providing broad access to well integrated medical care. Thus, management can potentially have positive effects on health as well as on spending. The state of Kansas, for example, has made some progress in using case management for the medically indigent population,[250] as has the state of Michigan through its Medicaid program.[251]

Outside reviewers can also "manage" care indirectly through such mechanisms as prescreening of hospital admissions, concurrent evaluations of the necessity for prolonged hospital stays, or retrospective review of utilization and claims. These practices are now common in large private health insurance plans, but less so in public plans.[252]

Of course, achieving improvements through case management depends on there being something to manage. Savings are possible where disjointed and perhaps over-generous coverage has led to previous overspending, so that cutbacks are not deleterious. But the main problem for the uninsured is prior *lack* of care, not over-service. One could implement managed care for a previously uncovered population, but the manager must be able to provide a minimum set of benefits—both primary care and necessary specialists, in addition to hospital care—well beyond what is currently available to many or most of those now medically indigent. Such management should make coverage less expensive than traditional open access insurance, but it will almost surely cost more than the patchwork of care now available to the uninsured—because more care will be delivered.

Mention should be made of two other major cost-containment ideas: provider and patient incentives to economize. Providers can be motivated to reduce their use of medical resources if they are prepaid some fixed amount, rather than being "reimbursed" for their incurred costs or charges as under the traditional practice of Medicare, Medicaid, and private plans alike. The 1980's have seen a virtual "buyer's revolution" of refusal to accept provider-dictated spending.[253]

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[250]*See* Hansen, *Kansas' Medical Coverage Programs for the Poor: A Targeted Approach Through State-Financed and State-Administered Programs*, in ACADEMY, *supra* note 136, at E-1.

[251]*See, e.g.*, McDonald & Fairgrieve, *Michigan's Experiment with Case Management*, 20 CLEARINGHOUSE REV. 423 (Special issue, Summer 1986).

[252]For private developments in managing health spending, see, e.g., J. CALIFANO, *supra* note 22; P. FOX, W. GOLDBECK & J. SPIES, *supra* note 22. Efforts are too numerous and varied to catalog here; many are reported regularly in such newsletters as COALITION REPORT (U.S. Chamber of Commerce, Clearinghouse on Business Coalitions for Health Action, Washington, D.C.) and MEDICAL BENEFITS (Kelly Communications, Charlottesville, Va). For public-plan developments, see, e.g., AFFORDING ACCESS TO QUALITY CARE, *supra* note 236, especially chapter 5 at 127 (Bartlett, *The Management of Medicaid Inpatient Hospital Expenditures*) and Chapter 8 at 201 (Neuschler, *Alternative Financing and Delivery Systems: Managed Health Care*).

[253]*See, e.g.*, J. CALIFANO, *supra* note 22.

Prepayment can result from several approaches. First, plans may simply set prices administratively and offer them to providers on a "take it or leave it" basis, as does Medicare with its prospective payment system for hospitals based on Diagnosis Related Groups (DRG's).[254] Alternatively, preset prices can be arrived at voluntarily through bidding or negotiation, or set on a mandatory basis by economic regulation, as are hospital rates in a number of states.[255] Referral or admitting physicians can also be encouraged to economize on specialists' treatment or hospital care by sharing savings with them.[256] One concern about economizing incentives is naturally that providers may *under*serve, just as generously rewarded fee-for-service practitioners may *over*serve.

Finally, patients may be encouraged to save in similar fashion—either by having to share in spending (cost-sharing through deductibles, co-payments, or co-insurance) or by being allowed to share in savings below expected amounts. However, as previously discussed, patient-oriented strategies are generally considered less desirable for poverty populations than for the insured middle class. A payment requirement to pay X dollars per visit may help insured patients weigh the cost versus the value of care without preventing them from proceeding; for poor people, the burden looms larger relative to their other needs and may deter them from getting care altogether.

3. Financing. a. Fiscal requirements.—How much financing is needed to cover the medically indigent? That obviously depends on one's definition of the problem and on how generous one is in addressing it. The potential range is $5-50 billion, with $15-20 billion a reasonable estimate for moderate initiatives. A minimal program might cover only the cost of non-elective, uncompensated hospital care that is already provided to "charity" patients. Such care totalled about $4-5 billion in 1986.[257] Funding such care through a public program would be the

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[254]*See, e.g.*, Bovbjerg, Held & Pauly, *supra* note 58.

[255]*See, e.g., id.*

[256]Some case management strategies do this, as noted *supra* notes 249-52. Similarly, some HMO's give their doctors performance bonuses. And some hospitals prepaid by Medicare have sought to reward physicians for holding down hospital spending. *See* U.S. GEN. ACCT. OFF., PUB. NO. HRD-86-103, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE (1986). Congress has acted to ban under Medicare and Medicaid any payment incentives to physicians from hospitals or risk bearing HMO's to reduce or limit services to patients. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9313, 100 Stat. ____, ____.

[257]The figure is the authors' rough estimate, with the following assumptions: The 1986 cost of uncompensated hospital care is $13 billion. Cohodes, *supra* note 36 (citing estimates by American Hosp. Ass'n). About one-third of such care goes to charity patients, as designated by hospitals themselves. Sloan, Valvona, & Mullner, *supra* note 31, at 19. Approximately two-thirds of such care is for non-elective services. *Cf. id.* at 30 (fully 42% of relevant hospital charges comes from two categories, childbirth and accidents — both non-elective services). Note that the estimate of $4-5 billion does not allow for an *increase* in hospital service generated by the knowledge among hospitals and indigents

minimal response to the problems of the medically indigent.

The highest reasonable estimate comes from assuming coverage for all of the uninsured and underinsured for a broad range of services to a very high level of medical spending—on the ground that in-depth coverage for all is needed to prevent catastrophic medical expenses from rendering anyone medically indigent. Full coverage implemented on a national basis could easily cost $50 billion dollars more a year than is now spent, depending on how rich a benefit package were provided.[258] This approach would constitute national health insurance, although it might not closely resemble the ambitious federal plans of the 1970's in design or implementation.

More reasonable estimates of a program to cover the medically indigent surely lie between the $5 and $50 billion extremes. As a rough guess, spending $50 a month only for those now uninsured who are below the poverty line would cost "only" about $6 billion the first year, whereas spending $80 a month for those with family incomes under two

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alike that more funds were available to cover charity care. Depending on the eligibility and payment rules applied under a new system, such an increase could be substantial.

[258]The $50 billion figure derives from assuming that an equivalent of 30 million uninsured person-years currently exist, with an additional 20 million underinsured (i.e., not protected against catastrophe). Benefits are estimated at $100 per month for the uninsured, half that for the underinsured: ($100/month/person × 12 months/year × 30 million person-years) + ($50/month/person × 12 months/year × 20 million person-years) = $48 billion. No allowance is made for increased spending due to people cutting their own coverage to rely on government help. Discussion: Some 35 million people were uninsured in March 1984, probably two-thirds of them for the entire year, one-third for part of the year, perhaps averaging six months, for a total of about 30 million person-years. Calculated from M. SULVETTA & K. SWARTZ, *supra* note 16, at 3. At least an additional 20 million are underinsured. This estimate is from the finding that in 1977 24%-37% of population was underinsured overall, *id.* at 19, whereas only 11% was uninsured at the time of survey, *id.* at 3. *See also* Farley, *supra* note 11. The $100 and $50 figures are reasonable guesses for moderate coverage. Average per capita personal health spending for the *entire* population for 1986 is estimated at $146 per month. Calculated from data in Arnett, McKusick, Sonnefeld & Cowell, *Projections of Health Care Spending to 1990*, HEALTH CARE FINANCING REV., Spring 1986, at 1, 3, 12. Spending of course varies greatly according to characteristics of the insured and of the benefits covered. *See, e.g.*, *id.* at 20-32. Medicare, for an aged and disabled population, currently spends some $180 per month for each beneficiary, not counting beneficiaries' own spending. U.S. OFFICE OF MANAGEMENT & BUDGET, THE UNITED STATES BUDGET IN BRIEF 46-47 (1986) ($67 billion in federal fiscal 1986 for some 31 million beneficiaries). Medicaid spends about $159 per month per recipient overall, although nearly half goes to a small fraction of eligible recipients receiving long term care. *Id.* at 44 ($23.7 billion federal, $19.3 billion state for 22.5 million FY 1986 recipients). Not all of these people are covered for the entire year, so the estimate is biased low. Federal spending in 1986 for the Federal Employees Health Benefits Plan averaged fully $221 per month per covered employee (each with an unknown number of dependents), not counting employees' share of premiums (about 25% of the total or 33% more than the federal share) or required cost sharing. U.S. OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT, Appendix, Fiscal Year 1986 I-V 7 (1986) [hereinafter U.S. BUDGET].

times the poverty level would cost some $20 billion.[259] In practice, it would not be sensible to cover everyone below some arbitrary level for 100% of the cost and no one above it at all. Such abrupt breaking points (or "notches," as they are often called) are unfair to those just above them, discourage beneficiaries from earning more (or reporting earnings), and encourage non-beneficiaries to drop to covered levels. An intermediate method is to provide graduated support in the boundary zone (often called "sliding scale" support), which probably would increase spending.

In comparison, states now spend about $20 billion a year in Medicaid,[260] and almost all are working hard to cut back its scope.[261] Moreover, states spent an additional $24 billion on hospitals and other health care in 1985.[262] Cities and counties together contributed somewhat less, about $18 billion on health care in 1984.[263] New funding for the indigent could displace some existing spending; this small "savings" would likely be overwhelmed by new spending generated by almost any new entitlement.

b. Funding sources and limitations. (i.) State taxes and federal preemption.—States and localities have numerous funding options through taxation or mandates on individuals, employers, providers, and insurers. In principle, any existing state tax could be used to fund programs for the medically indigent, whether they were public programs, like Medicaid, or private programs, like those considered in the next subsection. Traditionally, these taxes include the state income tax (for most states), city, county, and state property taxes, and sales and excise taxes. Any or all could be used for these purposes. States could appropriate general fund monies or they could dedicate a particular tax levy to help meet the needs of the medically indigent. Because state budgets are already hard pressed, new revenues are probably needed, and many people prefer to raise new revenue in some way related to health—by raising so-called "sin taxes" on tobacco and alcohol, for example. Nevertheless, it is clear that such taxes by themselves probably will not produce sufficient

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[259]About one-third of the uninsured are uncovered only during part of the year, Farley, *supra* note 11, so that they would not need new assistance for the full year. Also, the estimates do not include newly uninsured people taking advantage of new assistance.

[260]*See* U.S. BUDGET, *supra* note 258.

[261]*See generally* AFFORDING ACCESS TO QUALITY CARE, *supra* note 236; J. HOLAHAN & J. COHEN, *supra* note 18.

[262]U.S. BUREAU OF THE CENSUS, SERIES NO. GF84, NO. 3, STATE GOVERNMENT FINANCES IN 1984, at 2 (1985). Not all of such spending covers medical indigents, of course; much goes to particular classes of patients not based on income, e.g., victims of tuberculosis, crippled children.

[263]U.S. BUREAU OF THE CENSUS, SERIES NO. GF84, NO. 4, CITY GOVERNMENT FINANCES IN 1983-84 (1985) and SERIES NO. GF84, NO.8, COUNTY GOVERNMENT FINANCES IN 1983-84, at 2 (1985).

revenue,[264] and there is, of course, considerable political resistance to general tax increases.[265]

Therefore, funding that does not require direct taxation of individuals attracts considerable interest. Public funding can be provided, in part, by a tax or assessment on hospitals not providing a specified minimum amount of charity care. Under this approach, all hospitals could be required to provide a certain percentage of, say, their gross revenue as charity care. Hospitals providing less would be required to pay the difference into the fund.[266] Public policy makers may find such taxation by regulation attractive because it is "off budget," or at least off *their* budgets.

Adopting this concept would have the added benefit of eliminating "dumping" of non-paying patients as a way to hold down prices in the increasingly competitive hospital market. Although expensive, it would promote access to inpatient care for poor people, and the expense would be spread among paying hospital patients, largely insured patients. Of course, a standard definition of charity care, as compared to uncompensated care, would be needed to exclude bad debts of those capable of paying. And administration of this "program" would have to be left mainly to hospitals themselves.[267]

One might also attempt to reduce the number of uninsureds generally—not only the medically indigent—by mandating that employers provide health insurance to their employees. The state of Hawaii currently has such a program. However, a legal obstacle prevents other states from enacting similar programs. The federal Employee Retirement Income Security Act of 1974 (ERISA) interferes with state options through its regulation of employee benefit plans, both pension plans and welfare benefit plans.[268]

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[264]*See* Bartlett, *State Level Policies and Programs,* in ACADEMY, *supra* note 136, at 54, 60-61.

[265]*See supra* note 56.

[266]The Ohio task force dubbed this the "care or share" approach. GOVERNOR'S COMMISSION ON OHIO HEALTH CARE COSTS: FINAL REPORT (July 1984) (summarized in J. LUEHRS & R. DESONIA, *supra* note 61, at 37-38). Hospital taxes could also be based on net revenues, number of licensed or occupied beds, or other measures. Pooling similar to that described in the text already occurs within hospital rate-setting states and in Florida, where it helps fund an expanded Medicaid program. *E.g.*, Perkins, Dallek, Dowell & Waxman, *State-Based Financing of Indigent Health Care: Promise and Problems* 20 CLEARINGHOUSE REV. 372, 372-75 (Special Issue, Summer 1986).

[267]Such charity pooling seems impractical to extend to providers other than hospitals because there are so many of them.

[268]29 U.S.C. §§ 1001 *et seq.* (1982). Welfare benefit plans covered under ERISA include those that provide for medical, sickness, accident, and other non-pension fringe benefits. 29 U.S.C. § 1002(1) (1982). It should be noted that nothing in ERISA regulates the contents of welfare benefit plans; only reporting and disclosure requirements were enacted, according to conventional wisdom because Congress expected national health insurance soon to supercede all existing health plans.

Intending to make regulation of employee benefit plans exclusively a federal concern, ERISA expressly preempts state regulation of employee benefit plans.[269] One exception to this ERISA preemption of state law is that states may continue to tax and regulate insurance, that is, insurance companies and insurance contracts.[270] The Supreme Court has upheld such state regulation that mandates benefits to be covered in health insurance contracts, for example.[271] However, the Court noted that ERISA prohibits state regulation of an employer's benefit plan that is "self-insured" rather than placed with an insurance company, as this would not fall under the "insurance law" exception to the federal preemption.[272] Increasingly, especially in large employment groups, health benefits are self-funded.[273]

Given that ERISA prohibits state regulation of employee benefit plans other than through the avenue of insurance regulation, it would seem, a fortiori, that states cannot mandate that such plans exist.[274] Thus, the state of Hawaii is able to maintain its program only because of specific amendments to ERISA that "grandfather" the Hawaii Prepaid Health Care Act.[275] Of course, ERISA could be further amended to grant states the authority to require private insurance coverage.

It might be possible for states to achieve similar "insurance" goals through their power to tax employers. Clearly ERISA would not prohibit states from taxing all employers to fund care or coverage for the uninsured, for example, through a general payroll tax. Whether an income tax, because it is related to ability to pay, or a payroll levy, because it is related to the number of employees, is the more equitable method is open to debate. A payroll tax would, of course, tax employers already providing coverage in order to help those not now providing coverage, and could thus considerably hurt incentives to insure, especially in in-

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[269]29 U.S.C. § 1144(a) (1982).

[270]29 U.S.C. § 1144(b) (1982).

[271]Metropolitan Life Ins. Co. v. Massachusetts, 105 S. Ct. 2380, 2393 (1985).

[272]ERISA expressly provides that self-insured plans are not to be considered "insurers" or "insurance companies" for the purposes of state regulation. 29 U.S.C. § 1144(b)(2)(B) (1982).

[273]*See, e.g.*, Etheredge, *The World of Insurance: What Will the Future Bring?*, BUS. & HEALTH, Jan./Feb. 1986, at 5 (describes growth of self-insurance); *Self Insurers Outnumber Fully Insured Among Larger U.S. Corporations*, COALITION REP., April 1985, at 1.

[274]*But see* Director of Bureau of Labor Standards v. Fort Halifax Packing Co., 510 A.2d 1054 (Me. 1985), *prob. juris. noted sub. nom* Fort Halifax Packing Co. v. Coyne, 107 S. Ct. 430 (1986). In this case, Maine's Supreme Judicial Court held that because a Maine statute requiring severance pay was only operative when a benefit plan was not in existence, the statute did not "relate to" an employee benefit plan and thus was not preempted by ERISA.

[275]Pub. L. 97-473, § 302, 96 Stat. 2605 (1982) (codified at 29 U.S.C. § 1144(b)(5) (1982)).

dustries where many companies already provide no insurance. To maintain insurance incentives, employers could be allowed to deduct from the amount of payroll tax due any amounts contributed to health benefit plans (insured or self-insured) for their employees.

Would such provisions be impermissible regulation under ERISA? Perhaps so. Some courts have interpreted certain state plans of taxation as prohibited regulation and therefore ruled them preempted by ERISA. For example, a federal district court in Connecticut found a statute that imposed a 2.75% annual tax on employee benefit plans to be void and unenforceable because of ERISA preemption of state regulation.[276] Moreover, in protecting Hawaii's Prepaid Health Care Act in 1983, Congress specifically provided that Hawaii's ERISA exemption did not affect the status of "any state tax law relating to employee benefit plans."[277] Courts have interpreted this language to indicate that Congress intended to preempt all state tax laws insofar as they relate either directly or indirectly to employee benefit plans.[278]

Despite these rulings, a state may still be able to enact a payroll tax with deductions for health coverage such as the one outlined above. The rationale behind the deduction would be that these employers are already doing their part toward financing health care by providing some reasonable form of coverage. The legal argument runs as follows: First, the tax is analogous to a state corporate income tax that allows deductions for an employer's expenses incurred in maintaining employee benefit plans. Clearly, such state income taxes with such deductions have not yet been found to "relate to" employee benefit plans for purposes of ERISA preemption. A payroll tax with similar offsets should be afforded similar status.

Second, such a payroll tax does not "relate to" employee benefit plans because the employer is taxed, not the benefit plan itself. Moreover, unlike the voided Connecticut statute, the amount of deduction would not discriminate between insured and self-insured health benefits—the very distinction ERISA has been held to maintain.[279] For these reasons,

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[276]National Carriers' Conference Comm. v. Heffernan, 454 F. Supp. 914 (D. Conn. 1978). Connecticut's tax on premiums received by insurance companies was 2%, which meant that the tax structure operated as an incentive to use traditional insurance rather than ERISA-exempted plans. The court found this discrepancy (2% vs. 2.75%) to be "illustrative of the potential use of taxation as a means of regulation." *Id.* at 917-18.

[277]29 U.S.C. § 1144(b)(5)(B)(i) (1982).

[278]*See, e.g.*, Northwest Airlines, Inc. v. Roemer, 603 F. Supp. 7 (D. Minn. 1984); General Motors Corp. v. California State Bd. of Equalization, 600 F. Supp. 76 (C.D. Cal. 1984). *See* Shaw v. Delta Airlines, Inc., 463 U.S. 85 (1983); Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504 (1981).

[279]*See supra* notes 271-72 and accompanying text. Taxing self-insurance for the purpose of funding the deficits of state high-risk pools has also been invalidated on ERISA grounds. *See generally* Bovbjerg & Koller, *supra* note 211.

a combination payroll tax and coverage credit may not be considered as regulating employee benefit plans.

Similarly, states are also free to tax the insurance-like alternative plans such as HMO's and PPO's; again, they may offset charitable care these entities provide. Indeed, to some extent, states already do so through the imposition of insurance premium taxes.

The calculation of such taxes as well as set-offs for indigent coverage or care involve complex administrative questions. Nevertheless, such taxes could provide a useful basis for funding, and could equalize the burden imposed on competing financing and delivery alternatives—insurance companies, self-insurers, and alternative plans like HMO's and PPO's.

Mandates or taxes on insurers, on medical providers, or on employers may have more current political appeal than taxes on individual taxpayers. Indirect funding through mandates for individuals to insure themselves is another "off-budget" option for states to consider. It would be foolish to replace efficient group purchasing of health coverage by employers with more expensive individual policies; however, it might be sensible to fill in some gaps with individual mandates. One such mechanism is auto insurance, with a long tradition of individual requirements.[280] Automobile owners or drivers could be required to provide evidence of adequate health insurance as a condition of licensure, especially to cover the very large bills that often result from accidents and which contribute disproportionately to uncompensated care in hospitals.[281]

(ii.) Private revenue.—States can also seek to attract voluntary funding from individuals themselves (or their employers, if any) by mandating, or themselves running, subsidized insurance plans for some of the uninsured. The basic idea here is to encourage insurance coverage with subsidies while holding down costs with private contributions to premiums. This strategy presupposes that potential eligibles (or their employers) can afford to make a contribution, so it does not address the impoverished "hard core" of the uninsured. The approach would nonetheless address two groups who may be considered medically indigent—the uninsured working poor and the medically uninsurable. Public assistance could take the form of subsidizing eligibles' purchase of private coverage with cash, vouchers, or tax benefits; alternatively, governments could create publicly underwritten plans or insurance pools that eligibles could "buy into" at below-market rates.[282] It would be difficult, but

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[280]*See, e.g.* Widiss, *Introduction: Background and Perspective*, in NO-FAULT AUTOMOBILE INSURANCE IN ACTION: THE EXPERIENCES IN MASSACHUSETTS, FLORIDA, DELAWARE AND MICHIGAN (A. Widiss, J. Little, R. Clark & T. Jones eds. 1977).

[281]*See supra* note 257 on the contribution of accidents.

[282]Assistance to the working poor could readily take the form of providing a tax credit for workplace purchase of insurance, which would assist low and high income workers alike, rather than today's tax exclusion, which disproportionately assists upper-

perhaps not impossible, to structure such a new subsidy to aid those at high risk of failing to insure themselves, without having to subsidize too many otherwise similar people who already have coverage. This approach is experimental but merits close attention.

A second category of potential eligibles also needs public help to obtain coverage but can contribute themselves. These are nonpoor people otherwise uninsurable because of pre-existing adverse health conditions. In a number of states, state-run comprehensive insurance risk pools help these people buy standard policies at a surcharged rate.[283] The pools help a small fraction of even the uninsurable, and still fewer of the uninsured generally, and they do so at a high cost because even the surcharged premiums must be subsidized to meet high medical bills. Moreover, as now run, the pools do not help the indigent, but only those with the wherewithal to pay high premiums themselves. Although states may move toward targeted subsidies to help the low income uninsurable, high risk pools will provide only limited general help to the medically indigent.

4. Administration.—Any of the strategies just discussed can be implemented with varying degrees of public involvement. An entire public system can be created, using public funds and employees. Alternatively, government may specify what model(s) are desired and contract with private companies to administer the plan(s). Or government may help currently uninsured people "buy into" existing private plans, including those run privately for public employees.[284] Beneficiaries may be required to choose among multiple alternatives, e.g., HMO, PPO, private fee-for-service plan, public fee-for-service plan. Any of these alternatives may be funded with a mix of public and private revenues.

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bracket taxpayers. *See generally* Enthoven, *Health Tax Policy Mismatch*, HEALTH AFF., Winter 1985, at 5. The self employed could also be given tax benefits equivalent to those of group employees, as proposed in the Improved Access to Health Care Bill, H.R. 4742, S.2402-S.2403, 99th Cong., 2d Sess. (1986). Such major federal tax changes seem unlikely, given that comprehensive reforms have just been legislated. *See supra* note 48.

[283] *See supra* notes 11 & 26 for description of uninsurables; on the operation of state pools, see Bovbjerg & Koller, *supra* note 211.

[284] The state of West Virginia, for example, has a unique multi-employer group plan for public employees that already covers about 1 state resident in 8. The plan began at the state level, then expanded to cover local employees. The state is seeking foundation funding to study the feasibility of opening the plan to small, private employers as well. Remarks of Robert Chehig, West Virginia Public Employees Insurance Board, at Conference on Facilitating Health Care Coverage for the Working Uninsured: Alternative Strategies, Center for Policy Research, National Governors' Association, in Rosemont, Illinois (December 16, 1986). The two main implementation problems are how to prevent free-riding by small employers who would have bought coverage anyway and how to prevent adverse selection by high-utilizing new enrollees that would drive up the cost of the plan for all participants. Some judgmental underwriting (exclusion of bad risks) appears to be required. On the problems of pooling small groups, see generally Bovbjerg, *supra* note 24.

The state of Arizona, for example, has brought a number of these different methods together in the Arizona Health Care Cost Containment System.[285] AHCCCS, as it is known, is a comprehensive program of medical services provided to the medically indigent on a prepaid basis. Arizona runs the program with federal financial participation in lieu of conventional Medicaid. The program is privately administered under a state contract set by competitive bidding. The private contractor in turn contracts with local health plans for the provision of care, again on a prepaid basis through competitive bidding. HMO's, PPO's, and others are eligible to bid if they provide the requisite services in the designated areas. All providers are required to use primary care gatekeepers.

Currently, AHCCCS is being run as a demonstration project with federal Medicaid waiver authority, and results are not complete. The results on quality and access are not yet in, and there is some concern that people are not being well enough served.[286] However, the state itself is encouraged that it is delivering good quality care to a broad section of the medically indigent at a price less than that which prevails for Medicaid in somewhat comparable sunbelt states.[287] The state plans to expand AHCCCS to include non-Medicaid eligibles, including the working poor. This approach would mix public and private roles both in funding and in administration.

Numerous other initiatives incorporating these economizing ideas are under way at the state and local level, mainly initiated by public or quasi-public entities. The Robert Wood Johnson Foundation has sought to stimulate such trials with technical assistance and modest "seed money."[288]

As a matter of public administration, the need to implement controls over medical spending points toward local control because most medical markets are local. It is difficult to relate individually to providers or patients from a distance. Moreover, integrating new medical assistance with public hospital care might also occur more readily at a local level. Public "tastes" in welfare spending also vary considerably from place to place, certainly among states, and even within them. Some areas are well known for high taxes and high benefits, while other areas are known for the opposite.

Local control would also result in more experimentation than a national or even a state approach, assuming that the responsible localities

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[285]*E.g.*, J. CHRISTIANSON & D. HILLMAN, *supra* note 204.

[286]Kirkman-Liff, *Refusal of Care: Evidence from Arizona*, HEALTH AFF., Winter 1985, at 15.

[287]D. SCHALLER, ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM: ANNUAL REPORT, JULY 1984-JUNE 1985, at 91-118 (March 1986).

[288]ROBERT WOOD JOHNSON FOUNDATION, HEALTH CARE FOR THE UNINSURED PROGRAM (1985) (grant solicitation materials).

[289]*See generally* P. FOX, W. GOLDBECK & J. SPIES, *supra* note 22.

are large enough to support professional management. It is no accident that changes in private-sector health insurance occur market area by market area, through new entry by HMO's and PPO's and aggressive benefits management by large employers, third-party administrators, and business coalitions.[289] On the other hand, medical indigence is greatly affected by state-level decisions on welfare, Medicaid, hospital licensure, and insurance regulation, as well as by federal ERISA, Medicaid, and Medicare rules. Moreover, the ability of jurisdictions to raise revenues varies, so a broader approach also makes sense.

Given the current administration's attitude, the federal government appears to be out of the funding picture, although federal legislation continues to seek state and private solutions. For example, bills apparently to be reintroduced in the 100th Congress would require subsidized state high-risk pools, as well as revenue pooling for essential hospital care on behalf of those who cannot pay.[290] In any event, the short-term political reality, along with tradition and legal theory, suggest that combined state-local programs will be the dominant approach in the future as in the past.[291] Such approaches can combine state strengths in financing, pooling, regulation, and managerial expertise (available directly or through technical assistance to localities) with local virtues of provider and patient relations and flexible tailoring of programs to local desires and needs.

V. Affording Decent Coverage for the Medically Indigent

Conventional medical care is expensive, as is the insurance needed to cover it. One reason that it costs so much is the widespread belief that only the best will suffice (especially when care is heavily insured). Such attitudes seem to be changing, and certain economizing measures have become acceptable.[292] However, no "magic bullets" exist that can make the same conventional care or coverage affordable for all without considerable public subsidy or coercion.[293] Even with new economies, additional efforts to help the medically indigent will cost more than the current patchwork of assistance through Medicaid, public hospitals, regulatory requirements, and private charity, and society seems unwilling to contribute enough money, individually or collectively.[294]

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[290]In the 99th Congress, these bills were S.2402, S.2403, and H.R. 4742, The Access to Health Care Act; *see also supra* notes 63 & 282.

[291]*See* discussion of existing programs, *supra* notes 132-213 and accompanying text.

[292]The "buyers' revolution" in health financing has necessitated the acceptance of limits on insurance coverage and on patients' and medical providers' discretion to order ever more and more expensive health care. *See, e.g.*, J. Califano, *supra* note 22.

[293]*See* Bovbjerg, *supra* note 24, at 416 (same conclusion, for private coverage, voluntarily purchased).

[294]The most obvious demonstration of unwillingness to pay for medical indigents is states' reluctance to expand Medicaid to cover as many medical indigents as that program

Improvements seem to require one or both of two interrelated developments—greater willingness to pay or increased acceptance of new health "products" that offer lower but still decent levels of protection that people will be willing to finance. One major obstacle impedes both developments—professional and political desires (and legal expectations) for high quality medicine within a so-called single-tier system of health care for all, even the medically indigent.

With regard to willingness to pay, several trends offer some encouragement:

(1) More information about the plight of uninsured indigents should increase willingness to help them.

(2) Ordinary, middle-class people are increasingly at risk of medical indigency—because many have lost well-insured jobs, because many are beginning to work in small, less-insured workplaces, because high medical spending can exceed what was once a reasonable extent of coverage, and because more people are developing adverse medical histories that hamper obtaining insurance. Funding an adequate social safety net should appeal to those concerned about these risks.

(3) Finally, new mechanisms are being found to control medical spending,[295] offering the eventual prospect that a politically attractive, streamlined "product" will indeed emerge.

New products, the second needed development, must be able to implement sensible restrictions on the amount of care available and the prices paid in order to maximize the number of people who can be covered, even if this means somewhat more restricted access to less elaborate care. For those who now have no protection at all, some care is better than none. Indeed, existing medically indigent programs are experimenting with restricting access to providers, as are many middle-class plans.

Likewise, strong utilization control over the services delivered seems reasonable, and it may prove appropriate to insist on less expensive, nontraditional providers to cover certain services. It definitely makes sense to keep people out of the hospital wherever possible. Something like the Arizona AHCCCS program, perhaps with even a lesser package of benefits, may be appropriate depending on the local situation. Of course, any restrictions on providers or coverage can prove difficult to implement. Further experimentation is needed here.

This ongoing search for a decent, even if bare-bones, level of coverage is significantly hampered by ethical, professional, and legal reluctance to *allow* lower levels. Anything less than equal care for all is often castigated as "rationing" or unethical "second class" care. It faces legal impediments as well.

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will reach, even though the federal government pays half or more of the cost. *See supra* notes 236-39 and accompanying text.

[295] *See supra* notes 240-54 and accompanying text.

All the permutations of ethical-professional concern cannot be successfully addressed here. In brief, insisting on single-tier medicine for all in practice means eliminating any assistance for many of the least fortunate, because currently society demonstrably will not provide unlimited funds. Perfection is the enemy of the good here, even in the opponents' own ethical frame of reference.[296] Society accepts dual standards for other charity, whether public or private charity, even with regard to fundamental needs like food, housing, and clothing; why not in medical care?[297] Moreover, although today many politicians and providers pay lip service to the notion of "nothing but the best" for all, the reality differs. There are different delivery systems for the insured middle class, for veterans, for Indians, and for people using public hospitals. Accepting different programs for the medically indigent does not seem unthinkable.[298] Certainly, Medicaid pays less for physicians than do private insurance programs and thus buys much lower access for Medicaid patients. Yet, even with Medicaid, those within the eligible categories are clearly better off than non-eligibles in otherwise similar economic circumstances.

On a more philosophical level, it is notable that opponents seem to like to invoke the spectre of "rationing"[298] because it connotes denying people something to which they are entitled and could get, absent a meddling government.[299] However, labeling lower but decent care or coverage "rationing" is conceptually misleading and politically unhelpful. In the case of indigent medical care or coverage, the real argument concerns the nature and level of any entitlement; the "rationing" no-

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[296]As argued by one respected academic and advocate of public health programs: "[F]inally, the argument is advanced that special programs for poor people are fated to become poor programs—always the first for recissions. That argument has served too long as the refuge for neglecting poor people altogether." Miller, *The Role of Health Planning in the Provision of Complex and Not-So-Complex Services*, in THE ROLE OF HEALTH PLANNING IN THE COMPETITIVE ERA 43 (F. Sloan, J. Blumstein & J. Perrin eds. forthcoming 1987).

[297]For example, although it needs to be safe and fit for habitation, public housing need not supply middle class space or amenities. Food stamps cover a minimal diet at best, and no specific allowance at all is made for clothing. With regard to private charity, people seem to donate used clothing rather than new, and soup kitchens hardly offer cuisine competitive with many restaurants. It is true that some health care more immediately involves life and death than do food or housing, but access to true emergency care is not what needs to be limited. *See also supra* note 67.

[298]*Compare, e.g.*, Rosenblatt, *Rationing 'Normal' Health Care: The Hidden Legal Issues*, 59 TEXAS L. REV. 1401 (1981) *with* Blumstein, *Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis*, 59 TEXAS L. REV. 1345 (1981).

[299]Thus, for instance, gasoline rationing means queues for all, not merely for the poor. *Cf.* Bovbjerg & Held, *supra* note 233 (prefer "resource allocation" to "rationing" as descriptive term). "Rationing" as a term makes more sense if read in its older meaning of "offering limited quantities" (as in sailors' "rations" of rum), but the usual connotation of the expression is wholly different.

menclature merely assumes entitlement to full equality without demonstrating it or convincing taxpayers or others to fund it.

Hence, there are both practical and theoretical reasons for accepting separate programs for the poor. Beyond the ethical-political arguments lie practical legal problems. The law also contemplates equality of care for all, at least in that where care is provided, the same malpractice "standard of care" applies regardless of the patient's ability to pay.[300] Thus, where care is limited and a bad outcome occurs, providers (and insurers, as well) face possible liability.[301] In practice, legal exposure may reduce coverage because providers and funding jurisdictions may prefer to offer no nonemergency service rather than limited service or coverage with a liability risk.

How might liability rules protect the medically indigent without threatening willingness to help serve them at an affordable price? Precedents are not encouraging. Under malpractice law, a "reasonable minority" of practitioners may practice differently from the mainstream,[302] but the rule is grounded mainly in medical uncertainty, not differences in patients' ability to pay. The traditional locality rule, although now much eroded, is a second possibility.[303] The rule recognized local variation in the extent of medical talent and resources available. Some cases similarly hold it unnecessary for outlying hospitals to have the latest equipment available.[304] Such cases, however, focus on geographic rather than economic differences. More to the point is the distinction between specialists and general practitioners; specialists have a higher standard because they hold themselves out to patients as being more qualified (and, presumably, charge more as a result).[305] Public coverage that held itself out as only a decent minimum might seem analogous, but indigent patients have no real alternative, so the rationale is not really comparable.

Another relevant line of legal thinking—now quite academic and somewhat heretical—holds that malpractice law should govern only in the absence of contractual agreements specifying desired care (and dispute resolution procedures).[306] This approach suggests that different people

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[300]*See supra* notes 97-98, 107-08 and accompanying text. *Cf.* Atiyah, *Medical Malpractice and the Contract/Tort Boundary*, 49 LAW & CONTEMP. PROBS. 287, 292-98 (Spring 1986) (desire for egalitarianism a reason for tort, not contract, to govern malpractice).

[301]*See, e.g.*, Wickline v. State, 183 Cal. App. 3d 1175, 228 Cal. Rptr. 661, *rev. granted*, 231 Cal. Rptr. 560, 727 P.2d 753 (1986) (issue of liability for bad outcome after hospital stay cut short under third-party coverage rules).

[302]*E.g.* A. HOLDER, *supra* note 97, at 55-57.

[303]*E.g.*, Comment, *Standard of Care for Medical Practitioners—Abandonment of the Locality Rule*, 60 KY. L.J. 209 (1971).

[304]*E.g.*, Pederson v. Dumouchel, 72 Wash. 2d 73, 431 P.2d 973 (1967).

[305]Naccarato v. Grob, 384 Mich. 248, 180 N.W.2d 788 (1970).

[306]*E.g.*, Havighurst, *Private Reform of Tort Law Dogma: Market Opportunities and Legal Obstacles*, 49 LAW & CONTEMP. PROBS. 143 (Spring 1986).

can choose different levels of care for themselves. It could be argued that public beneficiaries had voluntarily accepted the restrictions in the program, so long as those restrictions were fully disclosed. However, this approach is not fully developed as a conceptual matter, much less as an accepted rule of law, and its relevance to poor people with few real choices is questionable.[307]

Perhaps the very notion that malpractice law should set the standard of care, in the sense of what care should be given, is over-broad. Partly through an unfortunate linguistic coincidence, the legal standard of "care," which originally meant the degree of carefulness required to be non-negligent, has come to mean also what services themselves are appropriate. Some rethinking seems called for here. The fact that a given insurance program or a given provider simply does not cover long-term care, mental health, or transplants—or for that matter, certain hospitalizations or hospitals—does not seem to be a failure of "care." It seems rather a personal or social judgment about the appropriate use of limited resources.

Malpractice rules and judicial process seem better suited to determining whether a technical mistake or oversight occurred than to deciding broader coverage issues. Thus, one solution to the problem might be to establish a program that defines and is limited to specific medical services and gives malpractice immunity to those who carefully provide those services. Whether the jurisdiction(s) establishing such a program can immunize themselves is another question.

VI. Conclusion

The main problem for the medically indigent is that they do not have enough money. And the main problem with health coverage for the indigent is that neither they themselves, their employers, nor their government(s) have bought them adequate protection. Medical providers have limited ability to provide charity care. Consequently, the medically indigent are disadvantaged in their access to medical care.

This Article has discussed various ways of organizing and financing coverage or care for the medically indigent. More public and private resources must be raised through some combination of taxation, regulation, and increased voluntary payment. The effort needed for even medium-level assistance is significant, perhaps $15-20 billion in the first year, or as much as states already spend on Medicaid.

If society in its various components is not willing to fund universal coverage of a conventional kind—and it currently is not—then society must settle for less, but in a constructive fashion. It must define a lesser but decent health "product," preferably in a subsidized, insurance-like

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[307]Atiyah, *supra* note 300.

form that offers beneficiaries choice among competing providers. Providers who participate in improving care for the indigent deserve praise, not malpractice suits for delivering only the care that is covered. They should receive protection from tort claims of misfeasance when they have in fact carefully complied with social norms of adequacy as reflected in coverage rules.

The need is urgent and the time to begin is now. It is better to start with a reasonable minimum, with the hope of later expansion, than to hold out for optimal plans that may never come to pass. Further arguing about "rationing" of care to the poor or the ethics of "two-tier" medicine merely postpones difficult coverage decisions, to the clear disadvantage of the medically indigent.

State Hospital Cost Containment: An Analysis of Legislative Initiatives

CARL J. SCHRAMM*

As a result of the success of various state efforts at containing hospital cost inflation and the encouragement such efforts have received in recent federal legislation directed at reducing Medicare costs,[1] a second wave of state initiatives directed at regulating hospital revenues appears to be breaking out in legislatures across the land. In 1983, three states enacted mandatory hospital rate-setting legislation.[2] In 1984, at least ten legislatures considered similar proposals. It has been suggested that in the next few years over half of the states will have adopted such measures.[3]

Observation of several recent legislative campaigns suggests an interesting similarity of parties, interests, tactics, arguments, and outcomes common to such efforts. Unlike many areas of public action where a small number of interests are contesting for resource control, any change involving hospitals has an immediate impact on a large number of groups. This Article attempts to identify the parties interested in state efforts to reform hospital financing mechanisms. It also describes the likely arguments and positions of each party, the dynamics of the various legislative tactics, and the probable outcomes.

This analysis is based on the author's experience and observations from 1980 to 1985 in eighteen states where hospital rate setting has been either: 1) successfully established by legislation, 2) enacted but not given life as an operating program, 3) considered by the legislature but not enacted, or 4) the focus of formal study by a gubernatorial or legislative task force or work group.[4] Because hospital rate setting has been the

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[1]Social Security Amendments of 1983, Pub. L. No. 98-21, tit. VI, §§ 601 *et seq.*, 97 Stat. 65 (codified as amended at 42 U.S.C. §§ 1395ww(b), (d) (1982 & Supp. 1985)).

[2]The three states were: Maine, ME. REV. STAT. ANN. tit. 22, § 381 (West Supp. 1986); Maryland, MD. HEALTH GEN. CODE ANN. § 19-209 (Supp. 1986); and Wisconsin, WIS. STAT. ANN. §§ 54.01 *et seq.* (West Supp. 1986).

[3]*See generally* INTERGOVERNMENTAL HEALTH POLICY PROJECT, STATE HEALTH NOTES (D. Merritt ed. March 1985).

[4]*See* AM. HOSP. ASS'N, STATE RATE-SETTING LEGISLATION: LEGAL ISSUES IN THE NEGOTIATION AND IMPLEMENTATION OF A STATUTE (1984); INTERGOVERNMENTAL HEALTH POLICY PROJECT, THE STATUS OF MAJOR STATE POLICIES AFFECTING HOSPITAL CAPITAL INVESTMENT (1984); NAT'L CONFERENCE OF STATE LEGISLATURES, HEALTH CARE COST CONTAINMENT LEGISLATION: 1983 LEGISLATIVE UPDATE FIFTY STATES (1983); NAT'L CONFERENCE OF STATE LEGISLATURES, 1984 STATE HEALTH CARE COST CONTAINMENT LEGISLATION (1984);

object of legislative action or governmental study in approximately twenty-three states,[5] the experience reported here, while representative, is not comprehensive.

I. Background on State Legislation

A. Forces for Reform

It is clear that the nation is struggling with the problem of unacceptable hospital costs. Evidence suggests that the health care delivery system is operating inefficiently.[6] Since the passage of the Medicare diagnostic-payment system in 1983,[7] falling hospital occupancy throughout the nation suggests that hospitals have in fact been overutilized.[8] Moreover, the large increase in the number of physicians entering the system[9] and the increasing age of the population[10] add a sense of urgency to the search for some means of reducing, or at least holding in check, the growth of the health care enterprise. Largely because hospitals are the most visible entity in the delivery system and have had the fastest relative increase in unit prices and absolute budgets,[11] they have been singled out as the object of public and private policy aimed at reducing overall health expenditures.

Partly as a response to the entry of government as a significant

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Schramm, Wren & Biles, *Controlling Hospital Cost Inflation: New Perspectives on State Rate Setting*, 5 Health Aff. 22, 23 (1986).

[5]*See supra* note 4 and accompanying text. Previous model state hospital legislation has been the basis for several legislative proposals and underlies the recently enacted West Virginia legislation. Schramm, *A State-Based Approach to Hospital Cost Containment*, 18 Harv. J. on Legis. 603, 658-78 (1981).

[6]*See, e.g.*, Dep't of Health & Human Services, Hospital Prospective Payment for Medicare: Report to Congress Required by the Tax Equity and Fiscal Responsibility Act of 1982 i-iii (1982); Dep't of Health & Human Services, Office of Ass't Secretary for Planning & Evaluation, Hospital Capital Expenses, A Medicare Payment Strategy for the Future: Report to Congress 1-33 (1986); Prospective Payment Assessment Comm'n, Medicare Prospective Payment and the American Health Care System: Report to the Congress 9-11 (1986) [hereinafter ProPAC Report on the American Health Care System].

[7]Social Security Amendments of 1983, Pub. L. No. 98-21, tit. VI, §§ 601 *et seq.*, 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(d) (1982 & Supp. 1985)).

[8]ProPAC Report on the American Health Care System, *supra* note 6, at 19-20.

[9]*See generally* The Coming Physician Surplus (E. Ginzberg & M. Ostow eds. 1984).

[10]*See generally* Fuchs, *"Though Much is Taken": Reflections on Aging, Health, and Medical Care*, 62 Milbank Mem. Fund Q. 143 (1984).

[11]Gornik, Greenberg, Eggers & Dobson, *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, Health Care Fin. Rev. 13, 43 (Supp. 1985) [hereinafter *Twenty Years of Medicare and Medicaid*].

payer of health care costs through Medicare and Medicaid, hospital prices have grown at a rate outstripping that of all other goods and services in the economy.[12] Consequently, it is not surprising that government has been the most active party attempting to reduce overall hospital cost inflation. Government interest is founded on two bases: government is attempting to react to the complaints of citizens about a politically sensitive issue, and government, as a payer itself through Medicare and Medicaid, is directly affected in its own budgets by cost inflation in hospital services.

Governmental approaches to the problem of inflation in certain markets can generally be characterized as regulatory in nature, i.e., a public agency typically becomes the mechanism by which prices are determined.[13] However, in the case of hospital costs, government has actively sought non-regulatory answers as well, including the establishment of alternative providers of care such as health maintenance organizations (HMO's) and the encouragement of financing mechanisms that result in more rational economic choices by consumers. The latter approach stimulates insurers to increase the presence of coinsurance and deductibles and to pay for second opinions in order to reduce the incidence of unnecessary surgery.[14]

Recently, however, concern with reducing costs in health and hospital care has grown so widespread that a larger number of private parties have taken an active role in influencing hospital prices. These include employers, unions, and health insurance companies. In response, providers, including hospitals and physicians, have unsuccessfully attempted voluntary price restraint as one possible solution.[15]

While there is widespread concern that hospital prices are rising too rapidly, few agree on how the problem should be attacked. However, several goals seem to be uniform objectives. The first is reducing the rate of increase in hospital cost inflation.[16] This has been the most widely accepted policy objective, largely because hospital prices have been rising faster than prices for other goods and services.[17]

In more recent years a second goal has become important, namely, reducing absolute levels of spending on health care. This objective began

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[12]*See, e.g.*, Levits, Lazenby, Waldo & Davidoff, *National Health Expenditures, 1984*, HEALTH CARE FIN. REV., Fall 1984, at 1, 8 [hereinafter *National Health Expenditures, 1984*]; PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE SECRETARY 12-13 (1985) [hereinafter PROPAC REPORT TO THE SECRETARY, 1985].

[13]*See generally* S. BREYER, REGULATION AND ITS REFORM 15-35 (1982).

[14]*See* PROPAC REPORT TO THE SECRETARY, 1985, *supra* note 12, at 13.

[15]*See, e.g.*, AM. HOSP. ASS'N, 1978-79 GOALS OF THE VOLUNTARY EFFORT (1979).

[16]Biles, Schramm & Atkinson, *Hospital Cost Inflation Under State Rate-Setting Programs*, 303 N. ENG. J. MED. 663 (1980).

[17]*Twenty Years of Medicare and Medicaid*, *supra* note 11, at 16-17.

to emerge with the recession of the early 1980's and with the immense growth of the federal deficit.[18] Related to reducing absolute levels of spending is the goal of reducing per capita spending on health care.[19] The emergence of these goals suggests that merely to reduce the rate of change in hospital prices, or to cut back levels of spending, is to avoid the issue of the drift of real wealth into the health care sector from other areas of social enterprise. The twofold growth of GNP shares consumed by the health sector in the post-Medicare era is evidence that wealth drift is the operative issue of concern.[20]

Therefore, the objective of those concerned over rising health care costs is some effective solution to the problem. While many have argued that competitive or market-based solutions offer the best hope of reducing the health care cost problem[21]—and, to be sure, increased competition in health care markets in the next few years will be observed — others believe it is inevitable that government will be the prime mover in restructuring the reimbursement system.[22] Government may act to reduce its own budget exposure and it may act for broader motives such as ensuring an orderly and politically acceptable allocation system.

B. The Road to Legislation—Four Premises of State Regulation

The first premise of government efforts to reduce costs is that legislative intervention and guidance are necessary if any system-wide change is to come about. For over a decade, hospital costs have been termed a serious, even critical, problem by many private interests. However, until very recently, there has been no evidence of any consensus, let alone action, among private sector actors. While there are increasing signs that some employers have taken an active interest in reducing health care costs,[23] it seems likely that government action will be necessary

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[18]The deficit in the federal budget increased from $59.6 billion in fiscal year 1980 to an estimated $207.7 billion in fiscal year 1983. OFFICE OF MANAGEMENT & BUDGET, FISCAL YEAR 1982, BUDGET REVISIONS, March 1981, at 11; OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 1984 M11 (1983).

[19]*See National Health Expenditures, 1984*, *supra* note 12, at 15-19; *see also* M. ZUBKOFF, I. RUSKIN & R. HANFT, HOSPITAL COST CONTAINMENT 579-85 (1977).

[20]Schramm, *Can We Solve the Hospital-Cost Problem in Our Democracy?*, 311 NEW ENG. J. MED. 729 (1984).

[21]*See generally* A. ENTHOVEN, HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COSTS OF HEALTH CARE 70-92 (1980).

[22]*See generally* Davis & Rowland, *Medicare Reform Options*, in RESHAPING HEALTH CARE FOR THE ELDERLY: RECOMMENDATIONS FOR NATIONAL POLICY (C. Eisdorfer ed., forthcoming).

[23]*See, e.g.*, *The Corporate Rx for Medical Costs: A Push for Revolutionary Changes in the Health Care Industry*, BUSINESS WEEK, Oct. 15, 1984, at 138-41.

to stimulate and channel change and to ensure that whatever change occurs serves the public interest.

The second premise is that the forum of policy change will be the legislature. Over the last ten years, the executive branch has not developed a solution acceptable to a sufficiently large coalition of interests; consequently, the executive branch has forfeited control of the health care cost issue to the legislature. Issues that do not yield to consensual solution within the executive branch must be solved, if at all, in the legislative branch. Moreover, the legislature, because it effectively controls the spending power and is responsible for taxing, has been required to act on health care costs from a budget perspective. Clearly, at the federal level, it was Congress that created the Omnibus Reconciliation Act in 1981, changing Medicaid programs substantially,[24] that fashioned the overall hospital spending limits in the Tax Equity and Fiscal Responsibility Act of 1982,[25] and that radically reformed the payment system by instituting diagnosis-related payment for Medicare in the Social Security Amendments of 1983.[26]

The third premise is that state legislatures have become equal to the Congress in developing new legislative approaches to the health care cost problem. As the federal ability to control rising health care costs seems less apparent, states have moved independently to control inflation.[27] Of course, the states retain regulatory jurisdiction over the hospital industry and can co-regulate with the federal government. But more important than constitutional authority is the rationale on which state action rests. Fundamentally, state authority is based on the economic dependence of hospitals on revenues generated in the state and on the nature of the hospital as a firm. Once Medicare and the federal share of the Medicaid program are removed, sixty percent of hospital revenues come from local sources.[28] In addition, because of the typical non-profit, charitable nature of the hospital, the state's interest in regulation is heightened. Thus, the economic rationale for state intervention seems well-established.

The final premise is that state legislatures may be the preferred policy locus. Because the nature of the cost problem varies substantially from state to state, both in terms of its magnitude and its causes, and because the constellation of actors and the strength of the various interest

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[24]*See* Omnibus Reconciliation Act of 1981, Pub. L. No. 97-35, tit. XXIII, §§ 2161-2184, 95 Stat. 357 (codified as amended at 42 U.S.C. § 1396n (1982 & Supp. 1985)).

[25]Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 101(a)(1), 96 Stat. 331-36 (codified as amended at 42 U.S.C. §§ 1395ww(a), (b) (1982 & Supp. 1985)).

[26]Social Security Amendments of 1983, Pub. L. No. 98-21, tit. VI, § 601 *et seq.*, 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(d) (1982 & Supp. 1985)).

[27]*See* Schramm, *supra* note 5, at 632-41.

[28]Gibson, Waldo & Levit, *National Health Expenditures, 1982*, 5 HEALTH CARE FIN. REV. 1, 19 (1983).

groups are different in each state, state legislatures are presumably more likely to craft acceptable solutions to meet local demands. Moreover, in our federal system, experience with a wide variety of state initiatives has the potential of increasing the development of more effective approaches to the problem of health care costs.[29]

Overarching each of the foregoing, however, is a fundamental concept of what role regulation plays in society. While many arguments have been advanced as to why regulation exists, it seems clear that in the case of economic regulation, the state is engaged in balancing interests that are not satisfactorily arbitrated in the market.[30] In response to actual or perceived market malfunction, the state enters to establish a distributional scheme (mainly by controlling entry and setting acceptable prices) that more adequately reflects an articulated social interest in the outcome of the economic exchange under scrutiny. In return for accepting a state presence, which necessarily reduces the discretion of the regulated enterprise, the state ensures some degree of security to the regulated entities. This quid pro quo reflects the fundamental nature of regulation: a formalized bargain where society exacts more acceptable behavior from the regulated firm in return for a promise of protection from some features of the unregulated marketplace.[31] Contemporary theory in state legislatures appears grounded on this exchange theory as opposed to the prevailing federal theory of unilateral delegation.

C. Primer on State Hospital Regulation

Modern state efforts at regulating the hospital industry began in the late 1960's.[32] In several states, controlling hospital cost inflation emerged as a matter for public concern and eventual legislation because of the public cost of care for the poor. In New York, where publicly supported care of the poor imposes a higher tax-related burden than in any other jurisdiction, inflation in hospital costs became a major issue in budget debates of the late sixties when it was apparent that New York City was close to financial collapse.[33] As part of the solution imposed by financiers, major reductions in spending, including for health care, were necessitated. Thus, the state established a program to supervise the

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[29]*See* Biles, Schramm & Atkinson, *supra* note 16.

[30]Breyer, *Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform*, 92 HARV. L. REV. 549, 553 n.17 (1979).

[31]*See* Stigler, *Theory of Economic Regulation,* in PERSPECTIVES ON THE ADMINISTRATIVE PROCESS 81 (R. Rabin ed. 1979); Wilson, *The Politics of Regulation*, in PERSPECTIVES ON THE ADMINISTRATIVE PROCESS 90 (R. Rabin ed. 1979).

[32]*See generally* Schramm, Wren & Biles, *supra* note 4, at 22.

[33]HEALTH CARE FINANCING ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, NATIONAL HOSPITAL RATE SETTING STUDY, VOL. VII: CASE STUDY OF PROSPECTIVE REIMBURSEMENT IN NEW YORK 2-8 (1980).

budgets of all hospitals, attempting to reduce spending for all payers, including Medicaid.[34]

The second state to establish a hospital cost containment program was Maryland, where hospital trustees were concerned that inner-city hospitals dealing with a higher-than-average caseload of indigent patients were in a state of fiscal stress and might be forced to close. As a result, trustees of the state's hospitals petitioned the legislature for an agency that would reduce hospital spending for all payers and distribute the expense of delivering care to the poor among all patients by establishing a uniform rate.[35]

In these two programs the seeds of the hospital regulation movement were planted. In both, the state stepped in to protect both the citizens who ultimately pay for care and the hospital system from financial insolvency related to uncompensated care. In each instance, the system of budget discipline imposed on the hospital was prospective payment for all care provided over a given period. Also, in both states all payers for care were made to pay the same price, thus allowing the costs of care provided to the poor to be redistributed over the entire patient population.

Shortly after the New York and Maryland legislatures established their programs, four other states initiated prospective hospital cost-containment programs.[36] Three of these states, Connecticut, Massachusetts, and New Jersey were in the northeast, where state legislatures had created substantial Medicaid programs in the mid-sixties. Because of the balanced budget requirements of state constitutions and recession-connected declines in tax revenues, these states were interested in reducing hospital cost inflation from a budgetary perspective. Another goal of the legislation was that both consumers and hospitals would benefit from a system that rationalized payment schemes among payers such that all citizens profited from reduced spending on hospital care.

Because of varying delays in collecting necessary financial information, all six states began regulating hospital rates at virtually the same time. Examination of the regulatory period from 1976 to the present

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[34]1965 N.Y. Laws 795 (codified as amended at N.Y. PUB. HEALTH LAWS § 2807 (McKinney 1985 & Supp. 1986)).

[35]*See* 1971 Md. Laws 627 (codified as amended at MD. HEALTH-GEN. CODE §§ 19-201 to 19-220 (Supp. 1985)).

[36]The states were Connecticut, 1973 Conn. Acts 117 (codified as amended at CONN. GEN. STAT. ANN. §§ 19a-145 to 19a-166 (West 1986)); Massachusetts, 1973 Mass. Acts 1229 (codified as amended at MASS. GEN. LAWS ANN. ch. 6A, §§ 31-77 (West 1986)); New Jersey, 1971 N.J. Laws 136; 1978 N.J. Laws 83 (codified as amended at N.J. STAT. ANN. § 26:2H-4.1 (West Supp. 1986)); and Washington, 1973 Wash. Laws ch. 5 (codified as amended at WASH. REV. CODE ANN. §§ 70.39.030 to 70.39.910 (West 1975 & Supp. 1986)).

has consistently shown statistically significant reductions in the rate of hospital cost inflation in the regulated states.[37] It is these data that in part account for the growing interest in hospital regulation at the state level.

D. State Activity to Date and its Classification

After nearly fifteen years, there are now several types of formal state-level initiatives to control hospital costs. The most extensive, typified by the first six states, is the regulation of total hospital revenues and the rates that all payers in the state are charged for care. In 1983, Maine, West Virginia, and Wisconsin enacted statutes similar to those in effect in the original six states.[38]

A second group of states are those that supervise hospital rates but do not have authority to set them. For example, in Florida, a public body exists to collect hospital price information and to disclose it publicly.[39] A third type of statute merely requires reporting of information on hospital prices to a state agency, which in turn may publish the information.[40] While it is still too early to judge the latter two types of efforts, ample evidence suggests that cost-containment programs are effective in direct proportion to the amount of government power vested in the regulating agency. Mere disclosure, for example, cannot be expected to be effective where consumers are fully insured against the costs of care.

II. The Parties and Their Interests

A. The Identities and Interests of the Twelve Groups

Most matters considered by legislatures evoke the attention of only two or three groups affected by a proposal. The groups include proponents (often private citizen/consumers, businesses, social reformers, and the executive departments of government) who seek legislative action on their behalf or on behalf of their cause; unqualified opponents of the proposal; and those who will be marginally disadvantaged by the measure and oppose its passage until the offending features have been discarded. When proposals that would limit hospital revenues are under consideration, however, at least twelve parties with distinguishable interests have been observed to take active roles. The presence of many interest groups makes the consensus necessary for the passage of leg-

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[37]Biles, Schramm & Atkinson, *supra* note 16.

[38]*See* Me. Rev. Stat. Ann. tit. 22, § 381 (West Supp. 1986); W. Va. Code §§ 16-5F-1 to 16-5F-6 (1985); Wis. Stat. Ann. §§ 54.01 *et seq.* (West Supp. 1986). See Appendix for a summary of a variety of state efforts.

[39]*See* Fla. Stat. Ann. §§ 395.501-395.514 (West 1986).

[40]*See* 1971 Cal. Stat. 1242.

islation problematic for two reasons: the process of multilateral negotiations is cumbersome and expensive, and the number of issues in dispute is extremely large.

As a result of the large number of interested parties, hospital rate-setting proposals present a curious legislative phenomenon; namely, unpredictable coalition behavior among the interest groups depending on the positions they adopt from state to state. Indeed, several of these groups have taken diametrically opposing positions in different jurisdictions. Compounding matters is the unpredictable identity of the "initiator" party from state to state.

What follows is a description of the interest groups and their respective positions on the question of regulating hospital revenue. The order in which they are presented does not reflect their importance to the legislative process. Once the groups and their causes are identified, the possible initiators of legislation are examined. Finally, the coalition behavior of the parties is explored and likely legislative outcomes—which ultimately depend on the nature and number of parties forming the most forceful coalition—are discussed.

1. Community Hospitals.—This group is composed of non-profit or voluntary, acute care community hospitals. More specifically, the interest group represents the position of professional administrators working in these hospitals. Their interests can often be distinguished from those who have a stake or interest in the hospital and its continued existence; for example, hospital trustees. As will be discussed in more detail below, community hospital trustees have traditionally represented what might be thought of as a long term local interest in the hospital.

The American Hospital Association (AHA), the national interest group whose membership is overwhelmingly composed of hospital chief executives, has vigorously resisted the adoption of rate setting. Reduced to its essence, the position of the AHA is based on the criticism that regulation reduces the managerial discretion of the professional administrator.[41] Professional administrators recognize that their interests might diverge from those of trustees, and the AHA has attempted to influence hospital trustees to its way of thinking. For example, the Association has established a separate trustee educational effort and has founded a magazine designed to influence trustees' perspectives.[42]

2. Hospital Trustees.—Trustees are more closely connected to the

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[41]*See Hearings Before the Subcomm. on Health of the Senate Comm. on Finance on State Hospital Payment Systems*, 97th Cong., 2d Sess. 236 (1982) (statement of the American Hospital Association); Knieser, *Free Market System Is Still the Best Answer*, 56 HOSPITALS 31 (1982); *see also* AM. HOSP. ASS'N, *supra* note 4; AM. HOSP. ASS'N, HOW STATES CAN OPT OUT OF THE FEDERAL MEDICARE DRG SYSTEM: A SUMMARY OF LEGAL ISSUES (1983).

[42]This magazine is TRUSTEE, published monthly by the American Hospital Publishing Co.

hospital's role in the community than many of the individuals who work in the hospital every day. To the extent that the hospital is viewed as a community-owned resource, often based literally on a financial trust dedicated to community welfare, trustees may view themselves as the custodians of a very special community asset.

In contrast to the essential "localness" of the trustee's interests, professional administrators participate in national labor markets, and their allegiance to a given institution often appears minimal. Whereas administrators, *qua* professionals, view themselves as important to the orderly functioning of the nation's hospitals, trustees represent community concerns and continuity of interest in the fortunes and successes of a local institution. Thus, from time to time, one can observe a clear divergence of interest between trustees and professional hospital leadership.

In the case of rate setting, a state presence may be desirable or at least less threatening to trustees who are members of the community elite and can informally make their voices heard in government circles. In Maryland, trustees initiated the movement that ultimately resulted in the creation of a state agency with authority to set hospital revenue limits; they saw government as the only means to distribute equitably the burden of uncompensated care and thus preserve the hospital system in a time of significant economic stress. Administrators, who as outsiders do not enjoy comparable government access, tend to view rate setting as an affront to their professional competence in making decisions related to hospital resource use.[43]

3. For-Profit Hospitals.—For-profit hospitals, whose political importance varies enormously from state to state depending on the share of hospital services provided by investor-owned hospitals, have always opposed rate-setting legislation. The basis of their opposition seems obvious; in regulated markets, firms have their profit level determined by a regulatory agency which customarily ties approved rates to actual costs of production plus a rate-of-return on investment. In such systems, investor-owned hospital executives believe that the freedom to seek maximum profit is removed. It appears that the resistance for-profit hospitals offer to state-level proposals to limit hospital revenue has little to do with the number of for-profit hospitals within a jurisdiction. Rather, the behavior of for-profit hospitals toward new rate-setting proposals suggests that the for-profit industry operates with the domino theory in mind—each additional state adopting hospital regulation, even if there is no significant investor-owned market share, increases the likelihood of regulation in other states.[44]

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[43]*See* Jolly, *Election Post-Mortem: Arizona Hospital, Business Health Cost Fight Fizzles*, BUS. & HEALTH, March 1985.

[44]*See* Statement by Cyndee Eyster, Director of State Legislation, Federation of American Hospitals, to the Special Committee on Health Care Cost Containment and the

4. Blue Cross.—Blue Cross plans were founded by hospitals as non-profit insurance schemes by which patients would fund hospital care through premiums.[45] As such, most state Blue Cross plans operate as specially chartered, non-profit, tax-exempt entities. Over the years, because of the close link between hospitals and Blue Cross (until the last decade overlapping boards of directors were common),[46] Blue Cross plans with larger market shares have enjoyed significant discounts from hospital charges in paying for their subscribers' care.[47] To the extent that rate-setting legislation would set hospital prices evenly among all payers, in an attempt to shift bad debt equitably among all hospitals and patients, Blue Cross will find the proposal objectionable because it will result in a major inhibition to maintaining what Blue Cross considers competitive rates.[48]

5. Commercial Insurers.—Because commercial insurance companies do not have direct contracts with providers as do Blue Cross plans (where the subscriber/patient stands legally as a third party beneficiary), but rather indemnify the insured/patient, they have not been able to extract discounts from hospitals. Commercial health carriers argue that as a result, virtually every other payer—because they contract directly with hospitals on behalf of a pool of patients, albeit an uncertain and unpredictable pool from the perspective of any one hospital—is able to extract some discount from hospital charges. Thus, commercial carriers argue that hospital administrators, in order to meet the demands for discounts made by direct payers (Blue Cross, Medicare, Medicaid, and workers' compensation), pass on the costs of this practice to those patients who pay full charges and seek indemnification from their insurers.[49] The practice of imposing higher charges on commercially insured patients, commonly referred to as cost-shifting, operates to disadvantage the indemnification carriers by raising their claims expenses. As a result, commercial insurers generally endorse cost-containment proposals which promise the equitable treatment of all payers.

6. Medicaid.—Every state except Arizona established a Medicaid program shortly after Congress passed the federal act in 1965.[50] Under the statute, Congress provided that roughly half of all costs of state programs would be met from the federal treasury provided that state programs included certain minimum benefits.[51] During the 1970's, Med-

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Human Resources Committee of the National Conference of State Legislatures (September 1984).

[45]S. Law, Blue Cross: What Went Wrong? 6-25 (2d ed. 1976).

[46]*See, e.g.*, Weller, *"Free Choice" as a Restraint of Trade in American Health Care Delivery and Insurance*, 69 Iowa L. Rev. 1351, 1370-71 (1984).

[47]S. Law, *supra* note 45, at 1-5.

[48]Ginzburg, *Hospital Cost Shifting*, 310 N. Eng. J. Med. 893, 895-96 (1984).

[49]*Id.* at 897.

[50]Twenty Years of Medicare and Medicaid, *supra* note 11, at 16.

[51]Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, §§ 121-122, 79 Stat. 343 (codified as amended at 42 U.S.C. §§ 1396 *et seq.* (1982 & Supp. 1985)).

icaid programs felt the financial strain of hyper-inflation in peculiar ways. State revenue is often more sensitive to general economic conditions because of sales tax, and the recessionary conditions of the seventies reduced state income substantially.[52] In states with relatively generous Medicaid programs, inflation in health care costs and a growing number of beneficiaries caused Medicaid expenditures to become a major part of state budgets by the 1970's.[53]

State budget officers have long seen Medicaid as particularly important to the fiscal condition of the state and have pressured Medicaid programs to reduce expenditures. Because federal law requires only minimum benefits and state enactments often expand the minimum, policy attempts to reduce costs have basically focused on three avenues. The first is to reduce the number of beneficiaries by readjusting eligibility standards for program coverage.[54] The second has been to pressure providers into giving Medicaid discounts against either charges or costs. These discount approaches have proceeded directly, for example by Medicaid unilaterally determining that it will not pay for inpatient care after, say, the twentieth day of hospitalization, or indirectly, by not increasing the payment for physician visits from amounts established as long as a decade ago.[55] The third approach has been to advance plans that would reduce the rate of inflation of costs in order to lessen the growth of the Medicaid expenditure from year to year.[56]

While governors may feel obliged to be sympathetic to the interests of hospitals and others who might be harmed by regulation, the condition of state budgets imposes a certain unavoidable demand on executives' allegiance. While cases exist where a state health department has publicly assumed a position on rate setting contrary to an executive's, such situations are rare and generally change once the governor imposes executive discipline.

7. Medicare.—For the most part, the federal government's role in the rate-setting debate at the state level has been minimal. In 1972, Congress sanctioned state hospital cost containment initiatives when it offered a waiver of Medicare reimbursement principles to those states experimenting with rate regulation.[57] Under this authority, several of the

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[52]THE REAGAN EXPERIMENT: AN EXAMINATION OF ECONOMIC AND SOCIAL POLICIES UNDER THE REAGAN ADMINISTRATION 157-219 (J. Palmer & I. Sawhill eds. 1982).

[53]Wing, *The Impact of Reagan-Era Politics on the Federal Medicaid Program*, 33 CATH. U. L. REV. 1 (1983).

[54]R. BOVBJERG & J. HOLAHAN, MEDICAID IN THE REAGAN ERA: FEDERAL POLICY AND STATE CHOICES 25-32 (1982).

[55]INTERGOVERNMENTAL HEALTH POLICY PROJECT, RECENT AND PROPOSED CHANGES IN STATE MEDICAID PROGRAMS: A FIFTY STATE SURVEY (1983).

[56]R. BOVBJERG & J. HOLAHAN, *supra* note 54, at 38-45.

[57]Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 222, 86 Stat. 1390.

rate-setting states were granted Medicare waivers in which the federal government agreed to pay its Medicare obligations according to the rate schedule set by the state agency. In 1983, Congress mandated that if certain requirements were met by a state rate-setting agency, the Secretary of Health and Human Services, acting through the federal Health Care Financing Administration (HCFA), must grant a waiver to the applicant.[58] Notwithstanding the nondiscretionary nature of this congressional directive, the Reagan Administration, acting through the Office of Management and Budget, has taken a decidedly hostile approach to Medicare waivers.[59] The Administration seems to perceive rate setting as an objectionable advance of regulation in society and to believe that it should not be encouraged as a matter of policy.

Medicare's non-participation may influence state legislation regarding rate setting in the future. To the extent that rate setting is attractive because it imposes the same rate schedule on all payers, thus making all payers share equally in uncompensated care, federal participation is critical. Apart from its philosophical objection, the Reagan Administration does not support the waiver option because of its perception that Medicare expenditures have been higher in waiver states than they would have been under normal Medicare reimbursement methods.[60] Notwithstanding evidence to the contrary,[61] it remains to be seen whether the Administration will attempt to revoke federal participation in existing waivers or grant waivers to the new rate-setting states.

8. Business.—In recent years, business leaders have become increasingly active in the debate over solving hospital costs. Indeed, the interest of business has served to refocus the problem away from concern over hospital cost inflation to concern over both the absolute level of hospital prices and aggregate hospital spending in a given community.[62] Business has joined other interests, most notably organized labor, in an attempt to force a discussion of what might be done in the community to reduce total hospital budgets. In many cases, employers have acted to reduce actual claims expense.[63] Generally this action has involved pressuring hospitals and Blue Cross plans to reduce both utilization by employees and the unit prices charged by the hospital to employees.

This movement is significant because it represents the first time a

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[58]Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, tit. I, § 101(a)(1), 96 Stat. 334 (codified at 42 U.S.C. § 1395ww(c) (1982 & Supp. 1986)).

[59]*See, e.g.*, Washington Report on Medicine and Health, Oct. 29, 1984, at 38.

[60]*Id.*

[61]S. Renn, The Efficacy of Waivers (1984) (unpublished paper, The Johns Hopkins Center for Hospital Finance and Management).

[62]*See generally The Corporate Rx for Medical Costs: A Push for Revolutionary Changes in the Health Care Industry*, BUSINESS WEEK, Oct. 15, 1984, at 138-41.

[63]*See, e.g.*, Jolly, *supra* note 43; Meyerhoff & Crozier, *Health Care Coalitions: The Evaluation of a Movement*, 3 HEALTH AFF. 120 (1984).

major division between a community's employers and a community's hospitals has been observed. It probably reflects in part the decision by employers over the last decade personally to bear the risk of hospital costs by self-insuring.[64] Self-insurance has forced many Blue Cross plans to play the limited role of claims administration. As a result, if an employer is dissatisfied with its claims expense, it may move directly against a group of hospitals in an attempt to secure lower costs.

9. Organized Labor.—Fringe benefits, including health insurance, have long been regarded by the leadership of organized labor as one of unionism's greatest achievements.[65] Thus, there has been little historic concern over the matter of rising hospital costs since higher costs have been viewed as resulting in more and better care. Employers paid for all or most of the costs of insurance, and union leadership has been largely disinterested in the absolute cost of these benefits. However, in recent times, the growth of fringe benefit expenses has been so great that employers have been more aggressive in bargaining. Unions have experienced negotiations in which little or no increase in take-home wages was possible because fringe benefit increases had eaten away all that the employer was willing to give or all that labor was able to bargain. Faced with such a vital challenge to the bargaining process, union leadership has increasingly concluded that hospital prices must be controlled.

The position of organized labor regarding hospital rate setting has been ambivalent in the past and continues to be ill-defined despite an increased sense of its importance. In some jurisdictions where hospital workers are organized, revenue control of hospitals is perceived as inevitably leading to reduced employment. Recently, however, organized labor has officially determined that it supports the concept of hospital rate regulation and has worked on behalf of regulation in West Virginia.[66]

10. Consumers.—Consumers have only recently emerged as a force in rate-setting legislation. Because they have traditionally been shielded from the true costs of health care by comprehensive insurance, consumers have been relatively indifferent to inflation in this sector of the economy. Insurance carriers have historically paid the costs of health care no matter how fast unit prices increased. Consumer apathy has been exacerbated by the very nature of hospital care finance, a field so complex

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[64]*The Corporate Rx for Medical Costs: A Push for Revolutionary Changes in the Health Care Industry*, BUSINESS WEEK, Oct. 15, 1984, at 138-41; *see also* Iglehart, *Big Business and Health Care in the Heartland: An Interview with Robert Burnett*, 3 HEALTH AFF. 40 (1984).

[65]*See* Dunlop, *Health Care Coalitions*, in PRIVATE SECTOR COALITIONS: A FOURTH PARTY IN HEALTH CARE 10-11 (B. Jaeger ed. 1982).

[66]WEST VIRGINIA LABOR FED'N (AFL-CIO), COMMITTEE ON POLITICAL EDUCATION, LEGISLATIVE REPORT SIXTY-FIFTH LEGISLATURE 16 (1982).

that it would require a substantial investment of time for individuals to comprehend the extent of their coverage and their exposure.

However, recent erosion of the fully protective nature of insurance, evidenced by increased copayments and deductibles, coupled with the erosion and threatened cutbacks in programs protecting the elderly and the poor, have forced more consumer advocates to turn their attention to the issue of rising health care costs.[67] Nearly all consumers have faced reductions in current coverage. Employer and union approaches have primarily involved reductions in the "first dollar" aspects of coverage in an attempt to make the consumer more price conscious and thus more judicious in the use of care.[68] Similarly, Medicare and Medicaid have been attempting to control provider (hospitals and physicians) expenditures for several years with little success. As a result, both programs have turned their attention to the patient/beneficiary as a means of curbing program costs in light of uncontrollable provider behavior.

11. Physicians.—Physicians always resist proposals to control hospital revenue. Their objections appear founded on the notion that if hospital revenue is constrained, ultimately the freedom of the physician to make choices related to the use of the hospital will be reduced. To the extent that physicians make a disproportionate share of their income from activities related to patient care in hospitals,[69] rate regulation is seen as a potential negative force on physician incomes. Others have suggested that physician resistance is based on the domino theory—if hospital prices are regulated, physician prices will be next. Recent action by the Congress in the 1984 Medicare amendments suggests this fear may not be groundless.[70]

12. Nurses.—Nurses have not played an important role in the rate-setting debate as yet. Where they have been visible, in only a handful of states, their resistance has been orchestrated by the state hospital association. Indeed, the only position taken by spokespersons for nursing interests has been that regulation has adverse effects on patient care.[71] Putting aside the quality issue, however, regulation will have no evident

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[67]*See* AM. ASS'N OF RETIRED PERSONS, 1985 FEDERAL & STATE LEGISLATIVE POLICY (1985).

[68]*See* Havighurst, *Competition in Health Services: Overview, Issues and Answers*, 34 VAND. L. REV. 1117 (1981); *see also* Goldsmith, *Death of a Paradigm: The Challenge of Competition*, 3 HEALTH AFF. 5 (1984).

[69]*See* Showstack, Blumberg, Schwartz & Schroeder, *Fee-for-Service Physician Payment: Analysis of Current Methods and Their Development*, 16 INQUIRY 230 (1979).

[70]*See* Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2306, div. B, tit. III, 98 Stat. 494, 1070 (amending 42 U.S.C. § 1395u(b) (1982)).

[71]*See* Schramm, *Economic Perspectives on the Nursing Shortage*, in NURSING IN THE 1980's, at 55 (L. Aiken & S. Gortner eds. 1982).

economic impact on nurses other than potentially reducing system-wide demand for nurses involved in inpatient care.[72]

Any description of the actors and their interests would be incomplete without noting that members of legislatures have their own interests to advance on the issue of hospital regulation. Most legislators have hospitals in their districts, which have tutored them on the causes of hospital inflation and the evils of rate setting. On the other hand, legislators inevitably deal with larger social issues and are compelled to behave with state-wide interests relative to the state's budget. This tension between serving the interests of their constituent hospitals and the needs of the state sometimes makes the issue of hospital cost control troublesome for legislators. The very nature of the hospital cost control problem, i.e., its complexity, persistence, and political intractability, makes it more amenable to a regulatory solution whereby the legislature delegates its authority to a continuing agency. This approach takes hospital decisions out of the hands of the legislature and places them in the "independent" branch of government where politicians cannot be held responsible for the outcome of the regulatory process.[73]

B. The Initiator

One of the most interesting aspects of the legislative process relating to hospital cost containment is the changing identity of the initiator of regulatory efforts from state to state. As one might suspect, the parties involved have somewhat different interests in each state. For example, in jurisdictions where Blue Cross market penetration is significant, sizable discounts against charges are often encountered. In these states, Blue Cross would clearly oppose any action to equalize rates among payers. On the other hand, in states where Blue Cross does not enjoy such discounts, Blue Cross might look upon rate regulation as a positive development designed to keep claims expense under control.

Based on experience to date, the parties that have first presented the idea of regulating hospital rates have included hospital trustees, governors, business, commercial insurers, and consumers. In each case, the interest in the issue is different. Trustees see rate regulation as a means of protecting hospitals from unequal exposure to bad debt expense, thus stabilizing the industry as a whole. Governors espouse the notion of controlling hospital inflation as a means of dampening the demand of state Medicaid programs for general funds. Business leaders have advocated regulation out of frustration with hospital inflation. Commercial insurers see regulation as a means of equity in payment and

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[72]*Id.* at 44-49.

[73]Kinney, *Coordinating Rate Setting and Planning in States with Mandatory Hospital Rate Regulation: What Makes a Difference?* (to be published in Journal of Legal Medicine).

protection against cost shifting. Finally, consumers have argued for rate controls to address the growing burden of insurance copayments and deductibles.

Obversely, certain parties have never supported rate regulation, much less acted as proponents. These include hospital associations and the investor-owned hospitals, medical societies, and nurses. The perception of each group is that if rate review legislation were to emerge, its economic interest might be impaired.

Several actors have been on each side of the issue in different states, and on each side of the issue in the same jurisdiction, but in different periods of time. Business has been divided on whether regulations are necessary. As mentioned above, many business leaders abhor the notion of encouraging the spread of regulation, notwithstanding their perception that hospitals will not establish spending restraints on their own. Likewise, organized labor has historically resisted hospital regulation as an implicit reduction in the benefits available to members and as a potential threat to the jobs of the many unionized hospital workers. A final example of ambiguous support is the action of Governor James Thompson of Illinois, who endorsed legislation designed to establish a hospital regulation agency and then failed to appropriate the funds needed to give it life.[74]

In conclusion, one is reminded of the work of Anthony Downs regarding the factors that make issues the subject of public, specifically legislative, attention. Downs argues that ideas move into public debate and are dealt with depending on the parties introducing the idea and the amount of public support the idea receives.[75] The crux of Downs' theory is that issues change through time, and predicting what action will emerge depends largely on who initially brings an idea to public attention. In the case of rate setting, because of the large number of interested parties, the importance of the initiator of the idea is overwhelmed by the identity of parties who support the notion.

C. Coalitions of Parties and Their Behavior

While the formation of coalitions is key in understanding the process that brings hospital revenue regulation about, there is little systematic knowledge about the operation of joint interests. There are, however, certain groups whose interests seem to coincide and others where certain antipathy is observed. The most commonly observed link is between commercial insurers and employers, if employers are at all active on the issue. Likewise, the bond between hospitals and Blue Cross seems certain.

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[74]*See* Crozier, *State Rate-Setting: A Status Report*, 1 HEALTH AFF. 74 (1982).

[75]Downs, *Up and Down with Ecology: The "Issue-Attention Cycle,"* 28 PUB. INTEREST 38 (1972).

In most cases, the similarity of positions between trustees and hospitals prompts joint activity to resist rate setting. Increasingly, where business has taken a positive stand, it is supported by organized labor, due largely to the formal existence of labor-management coalitions.

Just as certain parties find it in their interest to work together, the opposite also holds. Blue Cross and commercial insurers seldom appear to work together, just as physicians never join employers or unions in their positions. Similarly, for-profit hospitals will never work with organized labor. Medicaid, Medicare, and organized nurses generally operate on their own and seldom become an integral part of any coalition.

D. Likely Outcomes—Predicting Success or Failure

In the legislative process, it is always difficult to predict success or failure with any certainty. Considering the enormous diversity among state legislatures, it is virtually impossible to develop a paradigm that would be useful in forecasting the outcome of a drive to bring about hospital rate regulation. However, several postulates appear helpful in understanding the legislative disposition of hospital revenue control proposals. The first is that no one group can be successful in a legislative campaign. It appears that some majority of the more important actors must support legislation in order for it to pass. The second postulate is that active opposition by a small number of key interests can prevent passage. It appears that hospitals, working with Blue Cross, have generally been successful in preventing passage, especially if trustees have been active in their resistance. The third postulate is related; namely, no one group can prevent passage. Acting alone, hospitals, physicians, organized labor, and Blue Cross have been unable to prevent the passage of rate-setting legislation.

The net importance of these observations is that one must watch the joint behavior of the parties surrounding a legislative proposal. Success or failure lies in the coalitions that effectively work for or against the proposal.

III. Positions of the Parties

A. The Context of Argument in the Legislative Milieu

Having observed the legislative and executive process related to hospital rate regulation in several jurisdictions, it is possible to inventory the major positions advanced by proponents and opponents of regulation. Because of the apparent interest in the phenomenon, this Article gives limited attention to the arguments in favor of hospital rate regulation. Instead, it concentrates in more detail on the arguments offered by opponents. This approach should prove more useful in understanding

the legislative process, as legislation typically succeeds more by overcoming negatives than by being embraced for its obvious utility to society.

B. Why Hospital Rate Setting?

The statistical case that rate-setting achieves the objectives of legislation establishing a regulatory mechanism for hospital revenues is rather easily made and, indeed, is nearly universally confirmed by evaluative research on the effects of the regulatory process.[76] In the post-1976 regulatory era, the rate of increase in the cost of an average hospital admission has risen more slowly in the original six rate-setting states than in the 45 remaining jurisdictions—a finding of particular interest given the contrary inflationary experience of the six states in the pre-regulatory period.[77] Inflation in the cost of a hospital stay is a convenient proxy for measuring the effectiveness of the legislation in accomplishing its goal of reducing overall inflation.

C. Arguments on Behalf of Rate Setting

Given the success of the original state efforts to control hospital spending, it is interesting to examine the arguments advanced on behalf of hospital revenue regulation more carefully. It is important, however, to appreciate that for the most part, the success of rate setting has been linked to its ability to impose the same rate on all payers for hospital care. In most states, hospitals charge a variety of prices for the same services depending on the source of payment. Thus, cash paying patients and those insured by indemnity policies (commercial insurance) are referred to as charge-based payers because they pay for the actual cost of their care plus a markup to the charged price. Medicare and many state Medicaid plans have traditionally paid "reasonable costs," with no markup over the actual cost of providing care for the beneficiaries. In four of the original rate-setting states, the federal government, using its authority to waive Medicare regulations, agreed to reimburse hospitals at the rates set by the state agencies. In several states, Medicaid programs pay less than actual costs by setting lower-than-cost fee schedules for hospital care. In between are payers such as workers' compensation carriers that pay according to a fee schedule, Blue Cross plans which generally pay charges minus a contractually-agreed discount, and other

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[76]*See, e.g.*, Biles, Schramm & Atkinson, *supra* note 16; Sloan, *Rate Regulation as a Strategy for Hospital Cost Control: Evidence from the Last Decade*, 61 MILBANK MEM. FUND Q. 195 (1983). *But see* Mitchell, *Issues, Evidence, and the Policymaker's Dilemma*, 1 HEALTH AFF. 84 (1982); Morrisey, Sloan & Mitchell, *State Rate-Setting: An Analysis of Some Unresolved Issues*, 2 HEALTH AFF. 36 (1983).

[77]See Appendix, Fig. 1 for the rate of cost increases in the original six states and Figs. 2-7 for the experience in each of the six.

payers who have entered into agreements for discounts with the hospital. Clearly, the existence of multiple price schedules in hospitals suggests the existence of cross-subsidization of costs among patients depending on payment source.[78] In this respect, the average hospital operates as an implicit social taxing scheme on its patients.

The most important argument advanced for the initiation of rate-setting is that it clearly establishes strong incentives to reduce price inflation and ultimately to reduce the underlying costs of hospital care. To the extent that certain price levels are disallowed by the agency, the hospital must act to reduce costs.

The second most persuasive argument relates to the uniform price imposed in "all-payer" states; namely, that hospitals find all patients equally attractive. In states where different rates of reimbursement attach to different patients, equal access to hospital care is jeopardized. Hospitals clearly find certain patients more attractive than others. Likewise, where the state agency adjusts the uniform price in each hospital to reflect the cost of caring for poor patients, the hospital can be immunized against the risk of uncompensated care to those patients who have no form of insurance protection. Thus, discounts are awarded only to payers who offer demonstrated cost savings to hospitals, and no payer bears an unequal obligation to subsidize the care of uncovered patients. Related to inter-payer equity is the removal of any cause for hospitals to tax certain payers by "cost-shifting" unmet expenses from some patients to others.

Finally, in a package of attributes that might be characterized as management reforms, hospitals in regulated jurisdictions operate within a more predictable revenue environment, with a consistent set of incentives and payment methods from carrier to carrier. Further, due to the public collection of information, hospitals in regulated jurisdictions find evaluation of comparative performance easier.

D. Arguments Against Hospital Revenue Regulation

Opponents of hospital revenue regulation fall into two types: those who oppose regulation in general and those who object specifically to hospital rate control. The former adapt general economic arguments against regulation to the hospital setting. The latter argue from experience and use the record of hospital regulation in other jurisdictions as evidence of why regulation should not be adopted in the instant case. In the legislative milieu, these theoretical and experiential arguments are both used simultaneously and are often confused with each other.

1. Adverse Effects of Hospital Regulation in General.—The general

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[78] *See generally* B. Kinkead, Pricing Policy in the Hospital Industry (1984) (unpublished thesis, Johns Hopkins University).

arguments against hospital regulation are variants of well-known anti-regulatory reasoning that has developed over the hundred-year span of regulation in America. The most important generic argument relates to the effect of regulation on competition and the operation of market forces. Quite clearly the most commonly shared value in the American economy is the importance of freely functioning markets. Our commercial creed is based on the notion that markets act to distribute goods impartially in a manner that maximizes efficient production and equitable distribution. Notwithstanding the importance of this economic tenet, our history since the advent of industrialism has been rife with tension between parties attempting to control markets and maximize profits. In the early phases of industrialism, private interests appeared to consolidate capital, manufacturing, and distribution networks in order to reap "monopoly" profits. As government responded to perceived abuses in the market by enacting antitrust laws, it appeared as if government was seeking to regulate markets in the interest of the consumer. Most economists believe, however, that government regulation of markets merely reflects a transformation of the mechanism by which large commercial interests operate to protect their market shares and, consequently, their profits.[79] Thus, economists argue that while business interests vociferously oppose regulation in general as destructive of the working of the free market, many businesses enjoy and seek government intervention in ordering the market in which they operate.

The foregoing demonstrates that regulation has been ubiquitous in our economic order for nearly one hundred years. That regulation is antithetical to the operation of free markets is not clear from history, nor is it clear that consumers would tolerate an exclusively competitive market.[80] Indeed, as suggested above, the existence of regulation in an industry cannot be interpreted as the triumph of government over private interests. Rather, it suggests that a public presence has been introduced as an implicit bargain which occurs through our political process. Consumer/voters acting through their government have extracted price concessions in exchange for a government promise to protect the regulated industry from potential competitors and sagging profits. From this perspective, it is difficult to view the position that regulation is antithetical to competition and our free market tradition as anything but a historic and simple perspective on a tremendously complex issue.[81]

Closely linked to the argument that regulation is anticompetitive is the position that it inhibits innovation and experimentation. Much of what we value in the free enterprise system are the dynamics of the constant vying for market share. As a result, competitive firms are forced

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[79] *See* Stigler, *supra* note 31.

[80] *See generally* S. Breyer, *supra* note 13, at 1-35.

[81] *See generally* H. Commager, The American Mind (1950).

to innovate and experiment with new products. In a regulated market, it is feared that formal entry rules will inhibit new competitors, and that existing firms will no longer feel pressured to innovate and seek improved efficiencies. As a result, consumers will not benefit from lower prices over time.

A third general argument against regulation is that the transaction costs of regulation are excessive. For example, regulated firms must bear the additional legal and administrative costs of complying with rules that are not imposed by the marketplace as well as the process-related costs of seeking government approval for decisions. The burden of these process costs is passed on to consumers. Surveys by hospital associations suggest that the costs of complying with regulatory requirements add substantially to hospital costs.[82] Moreover, some argue that the costs of regulation are borne disproportionately by regulated firms and that larger firms bear relatively heavier costs than smaller firms. In any event, the distillate of these claims is that regulation is costly and that the burden of these costs does not fall neutrally on all firms.[83]

The final contention against regulation is that it intrudes into the decision-making authority of management. In the case of hospitals, it is further argued that regulation eventually invades the clinical decision making of physicians.[84] Regardless of the motive for regulation, the very nature of the process circumscribes the authority of managers and administrators. The existence of a public agency charged with setting operating rules for the industry and monitoring the behavior of regulated firms is the mechanism whereby the public's interest in the firm's decision making is presumably established.

The arguments against regulation in general meet peculiar difficulty when applied to hospitals. Regarding the theory of imposing a public interest in the decision making of the hospital, it must be remembered that the typical hospital was established as a public service entity, in nearly all instances as a non-profit, charitable institution.[85] It is therefore curious that hospitals would resist the imposition of a regulatory scheme whose rationale is to protect the public from the unbridled discretion of the regulated entities. Likewise, regarding regulatory costs in the hospital industry, many of the regulatory strictures already in place were developed by hospitals themselves in an attempt to develop uniform

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[82]*See, e.g.*, HOSP. ASS'N OF NEW YORK STATE, COST OF REGULATION, REPORT OF THE TASK FORCE ON REGULATION (1978); Lewin, Sommers & Sommers, *State Health Cost Regulation and Administration*, 6 TOLEDO L. REV. 647 (1975).

[83]*See* Cutler & Johnson, *Regulation and the Political Process*, 84 YALE L.J. 1395 (1975).

[84]*See* Zuckerman, Becker & Adams, *Physician Practice Patterns Under Hospital Rate-Setting Programs*, 252 J. A.M.A. 2589 (1984).

[85]*See* AM. HOSP. ASS'N, HOSPITAL STATISTICS, 1986 ed. 18-19, Table 5A (1987).

standards for their industry. Indeed, few if any industries in our economy have been so persistent in establishing self-policing bodies such as the Joint Commission on Accreditation of Hospitals (JCAH) or in seeking legislative delegation to these private regulatory efforts.[86] For example, a hospital can become a certified Medicare provider and qualify for federal payment simply by receiving JCAH accreditation.[87]

2. Specific Adverse Effects of Hospital Regulation.—The specific adverse effects of hospital regulation are generally associated with a particular interest which might be offended. For this reason, the problems with regulation will be examined from five perspectives.

a. Financial effects on hospitals.—Because revenue is affected, hospitals argue that regulation seriously erodes their short and long term financial strength. In the short term, it is argued that regulation affects the liquidity of the hospital, threatening its ability to meet current liabilities from current revenues. Through time, the additive nature of this revenue shortfall is said to threaten the hospital's solvency. As a result, accumulated capital resources, particularly endowment funds, are used to the long-term detriment of the hospital's fiscal stability.

On the basis of Stigler's theory of regulation, one would not expect this outcome.[88] Indeed, one would suspect that the presence of regulation would lead to a strengthened fiscal position for the hospital. Some evidence suggests that this is so. While hospital operating margins in the first six regulated states were lower than in other jurisdictions, through time hospitals in regulated states have experienced constant improvement in their margins relative to their past and to the non-regulated jurisdictions.[89]

Related to the argument that their fiscal status is jeopardized by revenue regulation is the hospitals' contention that the presence of a regulatory scheme operates as a liability in hospital capital markets. This contention is important because public capital markets have become increasingly important to hospitals in recent years.[90] Roughly a decade ago, most new capital investment in hospitals was funded through philanthropic gifts and accrued surpluses; now, however, most new construction is funded through revenue supported debt obligations sold by hospitals on the public bond market.[91] Should a hospital operating in

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[86]II A HOSPITAL LAW MANUAL, *Licensure* 1 (1980).

[87]*See* 42 U.S.C. § 1395bb (1982 & Supp. 1985). *See generally* Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care in the Public Interest*, 24 B.C.L. REV. 835 (1983).

[88]*See* Stigler, *supra* note 31.

[89]*See* Appendix, Fig. 8.

[90]*See generally* D. COHODES & B. KINKEAD, HOSPITAL CAPITAL FORMATION IN THE 1980's (1984).

[91]*Id.* at 51-53.

a regulated environment find its ability to place revenue bonds impaired, it could greatly increase the cost of debt service through the life of the obligation. While investors may have previously viewed the hospital rate-setting agency as an impediment to the hospital's ability to set rates at levels sufficient to support its debt service, hospital capital markets are now taking comfort in the presence of an agency which, among other goals, seeks to insure the hospital from bad debt (traditionally the greatest threat to an institution's long-term solvency), and which has had a demonstrable positive effect on operating margins.[92]

b. Adverse effects on medical practice and the organization of the market for care.—Perhaps the most important argument relating to the advent of regulation is that is has unintended and counterproductive consequences. Most of these "secondary" effects relate to changes in medical practice and a reorganization of the medical care delivery system in response to the establishment of a regulatory system.

These observations generally rest on the early utilization experience of hospitals during the first years of hospital rate regulation. Initially, rate-setting methods focused on controlling the rate of change in unit prices within the hospital for all services delivered to patients.[93] In response, quite naturally, hospitals began to increase the volume of units delivered in order to protect overall revenues. Likewise, there is some evidence that hospitals encouraged increased admissions, again to protect the level of revenues.[94] Soon after this response was observed, regulatory agencies developed new rate-setting methods which established positive incentives for hospitals to reduce overall costs. Thus, regardless of the change in the regulated price per unit of service, the hospital would attempt to reduce the overall budget. One such approach developed in Maryland is referred to as the Guaranteed Inpatient Revenue System.[95] Here, as in the recently adopted federal Medicare payment system, a hospital is paid a set amount per admitting diagnosis. Under the Maryland system, at the beginning of the fiscal year, the agency promises a prospectively agreed upon budget to a hospital producing care for a given number of cases of a certain complexity (based on its historic experience) as measured by diagnostic groups. Should a hospital deliver

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[92]*See, e.g.*, EFFECTS OF NEW JERSEY'S DRG HOSPITAL REIMBURSEMENT SYSTEM ON HOSPITALS' ACCESS TO CAPITAL MARKETS, REPORT OF THE HEALTH RESEARCH AND EDUCATIONAL TRUST OF NEW JERSEY (1983).

[93]HEALTH CARE FINANCING ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, FIRST ANNUAL REPORT OF THE NATIONAL HOSPITAL RATE-SETTING STUDY: A COMPARATIVE REVIEW OF NINE PROSPECTIVE RATE-SETTING PROGRAMS (1980).

[94]Worthington & Piro, *The Effects of Hospital Rate-Setting on Volumes of Hospital Services: A Preliminary Analysis*, 4 HEALTH CARE FIN. REV. 47 (1982).

[95]For a description of the Guaranteed Inpatient Revenue System, see Esposito, Hupfer, Mason & Rogler, *Abstracts of State Legislated Hospital Cost-Containment Programs*, 4 HEALTH CARE FIN. REV. 129, 143-44 (1982).

care under budget, it keeps fifty percent of all savings. Thus, the hospital has a strong incentive to improve internal efficiency and not to increase volumes.

A second undesired effect of regulation is the reordering of the market resulting from efforts to avoid the reach of the rate-setting agency. Increasingly, hospitals have been attempting to diversify into a large number of out-of-hospital ventures, including off-campus ambulatory surgical facilities, nursing homes, and diagnostic centers that are not traditionally within the contemplation of the enabling statutes. As a result, hospital rates may be held constant but overall spending on health care may accelerate as hospitals "unbundle" their services, intending to maximize revenue by developing whole new markets. This phenomenon points out one area for improvement needed in regulation, namely, control of capital decisions related to the situs of health care. Most communities are burdened with excess hospital capacity. Increasingly, it appears, more efficient and cheaper treatment sites such as ambulatory care facilities and HMO's are being developed. As this trend continues, the overinvestment in unnecessary hospital capacity becomes more acute. Therefore, states should consider removing inefficient capacity by closing or encouraging the merger and consolidation of existing facilities.[96]

c. Adverse effects on payers.—Obviously, if regulation operates well, payers should benefit by having their claims expense reduced. However, all payers will not be equally affected, just as all payers will not have an equal interest in hospital cost containment. Hospital revenue regulation may have beneficial results for some and harmful effects for others. Before examining the impact of regulation on various payers, it is important to remember that in non-regulated jurisdictions, real hospital costs differ substantially from one payer to the next.[97] To the extent that rate setting sets a uniform price for all payers, those presently enjoying price concessions (in many states, everyone except cash-paying patients and indemnity or commercial insurance carriers) will resist regulation. It is also important to note that from the perspective of some carriers, the fundamental premise of controlling hospital price inflation may not be in their interest. For those carriers who have their rates established by state insurance commissions (all carriers except Medicare and Medicaid), premiums are often set on the basis of claims expenses plus some allowance—usually a percentage of expenses for administrative costs. Thus, these carriers have actually benefited from rising a hospital costs!

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[96]*See, e.g.*, FINAL REPORT OF THE GOVERNOR'S COMMISSION ON OHIO HEALTH CARE COSTS (July 9, 1984); FINAL REPORT OF THE GOVERNOR'S TASK FORCE ON HEALTH CARE COST CONTAINMENT (State of Maryland, Dec. 14, 1984).

[97]*See generally* Ginzburg, *supra* note 48.

In regulatory systems where hospital costs will be controlled for a subset of payers (e.g., Medicaid and Blue Cross—a system once in effect in Massachusetts), costs will unavoidably be shifted to the unregulated payers. If the regulated cost of a stay is set lower than the average prevailing in the hospital, and the institution cannot shift its cost curve in the short run, it will attempt to shift the shortfalls incurred in serving patients covered by regulated payers to patients to whom the hospital is free to charge any price. As hospitals shift unmet expenditures, the unregulated carriers may experience a relatively higher rate of claims cost than prevailed in the pre-regulatory period. This cost-shifting burden has been felt most heavily by commercial carriers who, because of their indemnity relationship with their insureds, are among the last payers whose rates are included in regulation.[98]

Closely related to the issue of cost-shifting among payers treated unequally by rate setting is the burden an all-payer approach might place on the state treasury should Medicaid be required to pay at the same rate as other payers. Especially in jurisdictions where the state Medicaid program has unilaterally established payment schedules substantially below the rates charged to other payers, the legislature will find it difficult to deal with the initial costs of reestablishing Medicaid payment at equal levels. In 1982, for example, Governor Thompson of Illinois decided that even though he had endorsed a hospital regulatory program enacted by the legislature, the cost of bringing the state's Medicaid payments up to those required by the all-payer nature of the program was too high, and the legislation was never implemented.[99]

In addition to the adverse effects that concern both the commercial insurers and Medicaid programs, there is concern that Medicare obligations increase in states where the federal program reimburses at rates established by state agencies. The federal government may choose in certain jurisdictions to pay at rates other than its nationwide payment method.[100] As noted previously, in an attempt to stimulate state experimentation with all-payer rate setting, Congress recently enacted statutory language providing that any state enacting comprehensive regulatory programs that set hospital rates for all payers would qualify for a waiver of the Medicare payment method. The Reagan Administration has viewed the proliferation of hospital rate setting as an undesirable expansion of government regulation.[101] It has argued that where Medicare pays rates in accordance with all-payer systems, the total cost to the Medicare program exceeds what would have been paid under prevailing payment principles. However, recent studies have established that Medicare pay-

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[98] *Id.*

[99] *See* Crozier, *supra* note 74, at 74.

[100] *See* S. Renn, *supra* note 61, at 1.

[101] *See* Washington Report on Medicine and Health, Oct. 29, 1984, at 38.

ments in the regulated states where the federal government has waived its payment principles have in fact been substantially lower than they would have been absent the waiver.[102]

The final payer adversely affected by rate-setting legislation is Blue Cross. As noted above, many Blue Cross plans enjoy discounts against charges because of their close connection with hospitals, their policy of not contesting claims, and their assurance to hospitals regarding method of payment. To the extent that an all-payer system would reduce these discounts or limit them to their economic value to the hospital, Blue Cross will be adversely affected since it will have to compensate for the resulting increase in claims expense by increasing premiums in the short run.

d. Adverse effects on patient/consumers.—Two arguments are advanced relating to the adverse effects of regulation on patients. The first suggests that one of the inevitable outcomes of regulation is the rationing of care. This argument holds that when hospital budgets are constrained, less care will be delivered and some hospital needs of the population will go unmet. The argument assumes that productivity within the hospital cannot be improved and that the level of hospital care currently delivered is medically necessary. Indeed, the weight of all the evidence related to this question indicates that we are oversupplied with hospitals.

The second adverse consequence of regulation from the patient's perspective is its potential impact on the quality of care. In reasoning similar to that underlying the rationing argument, opponents of hospital revenue limits suggest that with fewer resources at the physician's command, the patient will be deprived of necessary services and supplies for maximum quality care. Because there are virtually no scientific measures of quality available, any statement about quality can be nothing more than expert opinion. It could, in fact, be argued that by setting resource constraints on hospitals, one of the benefits to emerge will be strong incentives to examine treatment outcomes more carefully so as to optimize resource use.

e. Adverse effects on hospital employees.—The final category of arguments against rate setting is that it will have adverse effects on those who are economically linked to the continued well-being of individual hospitals. While the number of individuals potentially affected by a reduction in spending on hospital care is extremely large, hospital employees are likely to be the most immediately affected by any potential reduction of hospital revenue. One reason why this group receives such attention is that if a hospital is to keep its operating expenses in line with permitted revenues, it must focus attention on labor costs. Labor costs alone account for over sixty percent of hospital expenses.[103]

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[102]*See* S. Renn, *supra* note 61.

[103]Am. Hosp. Ass'n, Hospital Statistics 23 (1984).

Concern over the impact of hospital regulation on employment is most commonly articulated in two arguments. First, hospitals will move to reduce labor expenses before any other cost-cutting approaches are taken. Obviously, because labor expenses account for such a high share of total costs, attention will be focused on reducing labor costs by layoffs and/or reductions in pay levels. In the case of layoffs, enormous political pressure builds on local officials to seek ways of expanding the hospital's budget in order to protect jobs. In the case of wage reductions, employees generally find such steps enormously unnerving to their sense of security, and the hospital adopting such a strategy may jeopardize organization morale.

The second labor-related argument is akin to the first but reflects a more subtle approach to reducing labor costs. It involves the substitution of higher-skilled with lower-skilled and lower-paid workers. For example, faced with new budget constraints, a hospital might attempt to substitute registered nurses with lower-paid practical nurses, or it might attempt to use nurse anesthetists in conjunction with physician anesthesiologists. There is some evidence, however, that in regulated situations some hospitals attempt to improve efficiency by replacing lower-skilled persons with fewer, more highly paid personnel.[104]

IV. Discussion

The issue of regulating hospital rates will grow in importance in the future. Indeed, state legislative activity in this area will increase, as will other avenues to establish a formal role for state government in the regulation of hospital finances. One of the most interesting lessons from observing legislative proceedings in eighteen states is the unpredictability of the outcome. As mentioned at the outset, the multiplicity of parties and the inconsistency of their coalition behavior from state to state make the legislative process very difficult to control, and often it appears a risky investment for those seeking to enact rate-setting laws.

Examining the legislative outcome in several states suggests the difficulty of working through legislation relating to hospitals. Of the eighteen states where legislation has been proposed or introduced during the last three years, laws have emerged in only three. While it is difficult to draw comparisons with other types of legislation, this success rate seems particularly low. On the other hand, previous observations suggest that there is a long gestation period for statutory proposals to limit hospital revenues. Moreover, the hospital industry nearly always ranks among the largest in terms of aggregate budgets in any state.

In response to the unpredictability and difficulty of pursuing a legislative program, recently it appears as if those seeking cost contain-

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[104]Schramm, *supra* note 71, at 45.

ment through the regulation of hospitals have taken new non-legislative approaches. By far the most dramatic has been the referendum attempt conducted in Arizona in the fall of 1984. Here, a coalition of major businesses interested in the establishment of a regulatory system for hospital budgets was urging a rate-setting bill upon the state legislature.[105] The hospitals' opposition was extremely strong and the legislature was apparently deadlocked. As an avenue for circumventing the legislature, the employer coalition ran a successful drive for a state-wide referendum in November of 1984. The legislature similarly developed several proposals related to hospital costs and placed them on the November ballot. Likewise, the hospitals developed a referendum proposal calling for limited regulation. In all, five regulatory proposals went before the voters. None passed despite what appeared in exit polling as a strong commitment to the idea by a majority of the voters. Explanations of the results vary, but the important observation here is that while the legislative route may prove difficult, the shortcut of referenda seems equally if not more unpredictable. Similar referendum campaigns have been discussed in other states, but since the Arizona experience, interest in the idea appears to have declined.

An emerging alternative to hospital revenue legislation seems to be attempts to change the underlying causes of the problem of high absolute hospital cost. In general, these approaches appear to focus on two separate issues—one institutional and the other more market-oriented. The first relates to the oversupply of hospital beds. For over twenty years, the connection between excess hospital beds and high costs has been recognized and has motivated policy at both the federal and state levels. In the last few years, however, with admission rates, length of stay, and overall occupancy falling in the nation's hospitals, the issue of excess capacity has taken on added importance from the perspective of reducing hospital costs. This results from the now widely observed phenomenon of hospitals attempting to compete with each other to fill beds—often at the risk of unnecessary hospitalizations—and from the costs of carrying overhead expenses on unfilled beds. Several states have recently published studies showing that as much as one third of their bed supply is unneeded.[106] As a result, the states are taking action to remove hospital beds through a series of legislative proposals that involve redeveloping hospital capital into other uses, public "buy-outs" of existing hospital debt, and exemptions to antitrust laws in order to encourage mergers and consolidations between hospitals.[107]

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[105] *See* Jolly, *supra* note 43.

[106] *See generally* Ohio and Maryland Commission reports, *supra* note 95.

[107] *See* INTERGOVERNMENTAL HEALTH POLICY PROJECT, *supra* note 4.

The market approach involves several states moving to payment mechanisms, principally for Medicaid, that revolve around fixed unit prices for given diagnoses. Similar to the federal diagnostic related group (DRG) system of payment recently imposed by Medicare, state Medicaid programs are looking to the unit price system as a means of forcing hospitals to cut their costs or suffer financial loss in treating the Medicaid population. In a similar vein, some states have promoted health maintenance organizations (HMO's) as a means of reducing hospital utilization. In Wisconsin, for example, a plan to put state workers into HMO's has stimulated rapid development of similar organizations in the state.[108]

The final observation related to state hospital rate regulation regards the role of the federal government in the development of future state initiatives in this area. In the past, the federal government has encouraged state efforts at controlling the hospital marketplace principally through Medicare waivers. As mentioned, under this authority the federal government cedes to certain rate-setting states the power to establish the rate at which Medicare pays hospitals for treatment of the Title 18 population. Currently, however, continuation of the waivers in the four states that qualified seems tenuous,[109] and the granting of new waivers, although recently encouraged by Congress, seems less and less likely under the current Administration. Fundamentally, the Reagan Administration has opposed Medicare waivers on the basis that they encourage regulatory solutions to social problems and represent the inevitable expansion of government.

In response, several new state rate-setting laws, such as that of Maine,[110] eliminate the need for Medicare participation in the regulatory scheme. Thus, Medicare is "carved out" and does not participate in the otherwise all-payer nature of the system. As a result, hospitals treating Medicare beneficiaries must operate within the DRG payment limits for these patients, while all other payers operate at the rates established by the state. Under this system, Medicare cannot participate in savings that accrue to other payers, and hospitals might make substantial profits from the Medicare population, at least in the initial years of the federal DRG system. Increasingly states will attempt to avoid bringing the federal government into their plans for controlling hospital costs both because the federal government is hostile to such state initiatives (something of an irony given the interest the current Administration has in state participation in other issues), and because the states are discovering that the systems can operate adequately without Medicare participation.

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[108]*See generally* Andreano, *Wisconsin Health Care Reforms Blend Tighter Regulation and Competition*, BUS. & HEALTH, Jan./Feb. 1984, at 47.

[109]*See* Washington Report on Medicine and Health, Oct. 29, 1984, at 38.

[110]ME. REV. STAT. ANN. tit. 22, § 381 (West Supp. 1986).

V. Afterword

What makes for success in the legislature has little to do with successful administration of its product, namely, a policy initiative embodied in statute. If the legislative effort is to yield a successful solution to the ultimate problem, the statutory scheme and the legislative intent must be transformed into a properly functioning agency and program. Necessarily, the legislature must enact statutes that embody the best contemporary thinking about the problem and its solution.

However, the best laws do not assure an acceptable solution to the problem. A good example of the difference between statute and performance exists in the comparison of the Maryland and Washington statutes and their success in containing hospital costs. The Maryland statute was enacted in 1971 and provided for comprehensive control of all hospital budgets in the state.[111] Shortly after its enactment, the Washington legislature passed a bill[112] modeled on the Maryland law, incorporating all of the features of the Maryland drafters. After a decade of experience, Maryland's agency was able to point to statistically significant reductions in hospital cost inflation and overall budgets,[113] while no significant effect on costs was discernible in Washington throughout the period.[114]

The absence of effect in the one state and success in the other suggest only that the system envisioned in the law itself is not the controlling essential. It merely points up the importance of several factors which are necessary to make hospital cost control a reality. The first, obviously, is continuing commitment on the part of the legislature to the importance of the issue. Second, once the delegation by the legislature is complete, the more important factor is the support of the state's executive. Continuous reinforcement by the governor is necessary if the agency is to be protected from the enormously powerful political forces concerned with the administration of the regulatory system. Third is the independence of the agency; good appointments by the governor and insulation from political pressure are requisites for an effective implementation of the legislature's intention. Finally, and of overwhelming importance, is the presence of a strong and professional staff for the

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[111]1971 Md. Laws 627 (codified as amended at Md. Health-Gen. Code Ann. §§ 19-201 to 19-220 (Supp. 1985)).

[112]1973 Wash. Laws ch. 5 (codified as amended at Wash. Rev. Code Ann. §§ 70.39.030-70.39.910 (West 1975 & Supp. 1986)).

[113]Coelen & Sullivan, *An Analysis of the Effects of Prospective Reimbursement Programs on Hospital Expenditures*, Health Care Fin. Rev., Winter 1981, at 1; Cohen & Colmers, *ReViews: A State Rate-Setting Commission*, 1 Health Aff. 99 (1982). *But see* Mitchell, *Issues, Evidence, and the Policymaker's Dilemma*, 1 Health Aff. 84 (1982).

[114]*Cf.* Coelen & Sullivan, *supra* note 113.

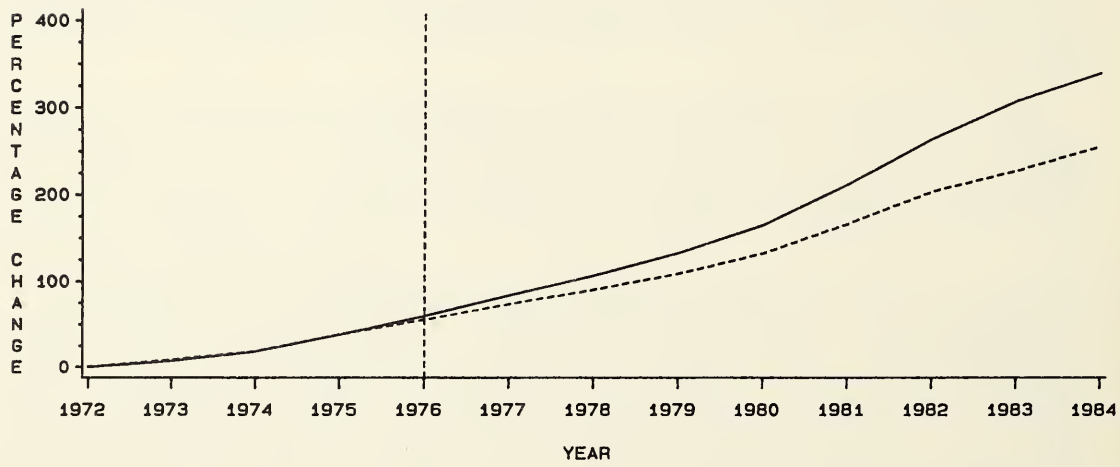
agency. Without a skilled and politically neutral staff, the rate-setting experiment will not succeed.

The foregoing analysis underscores the observation of one analyst that "good people cannot make a bad law work, just as bad people cannot make a good law work." Good laws are necessary to give force to a strong rate-setting program, and public-spirited people of determination must be encouraged to administer the will of the people as expressed through the legislature.

APPENDIX

FIGURE 1.

PERCENTAGE CHANGE SINCE 1972
IN EXPENSE PER ADMISSION (ADJUSTED)



LEGEND: ---- MEAN REGULATED 6 —— MEAN NONREGULATED 45

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FIGURE 2.

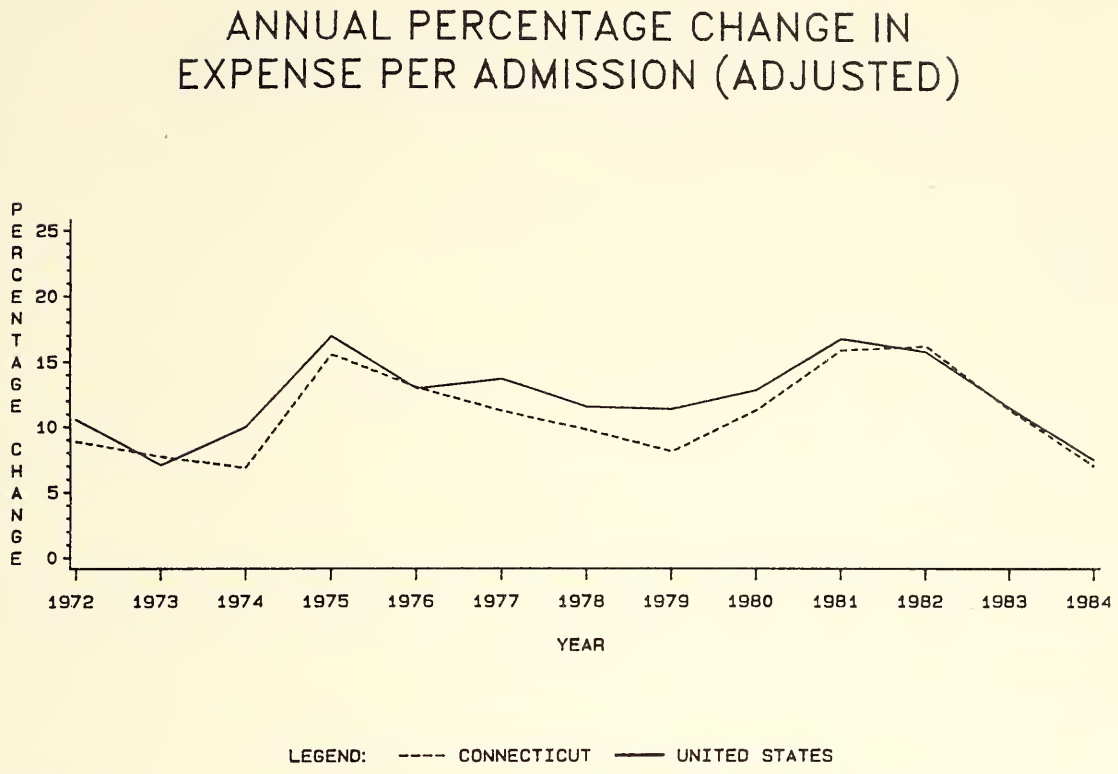


FIGURE 3.

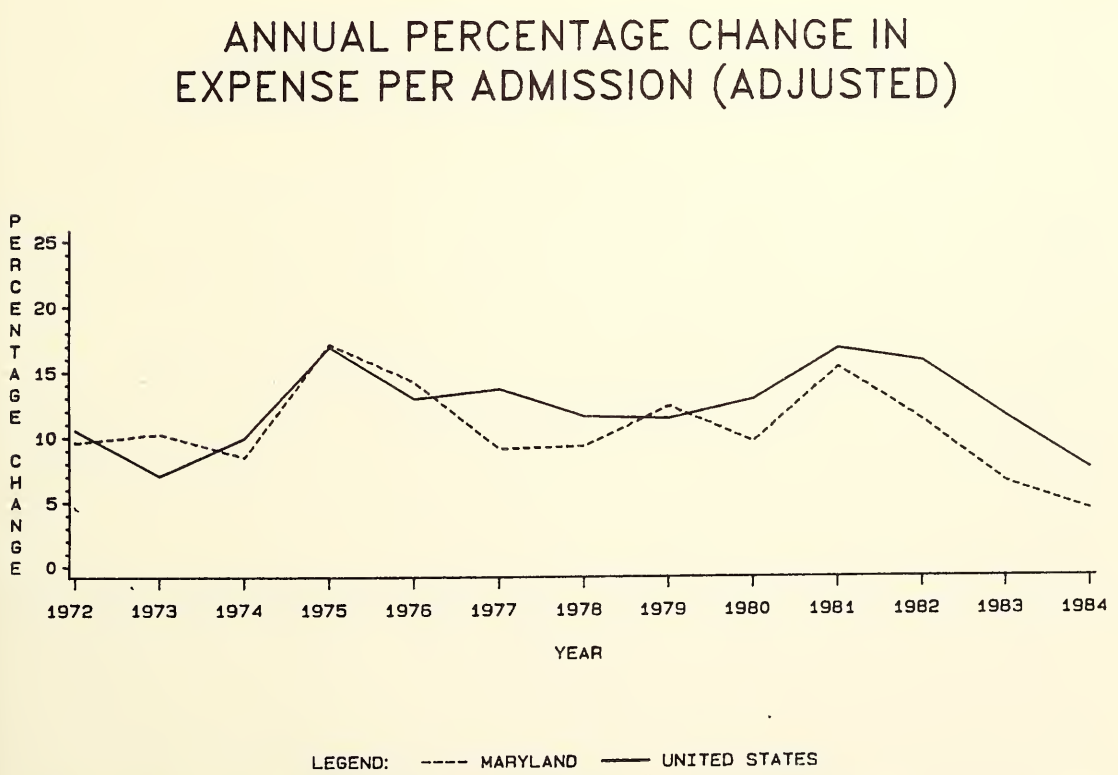


FIGURE 4.

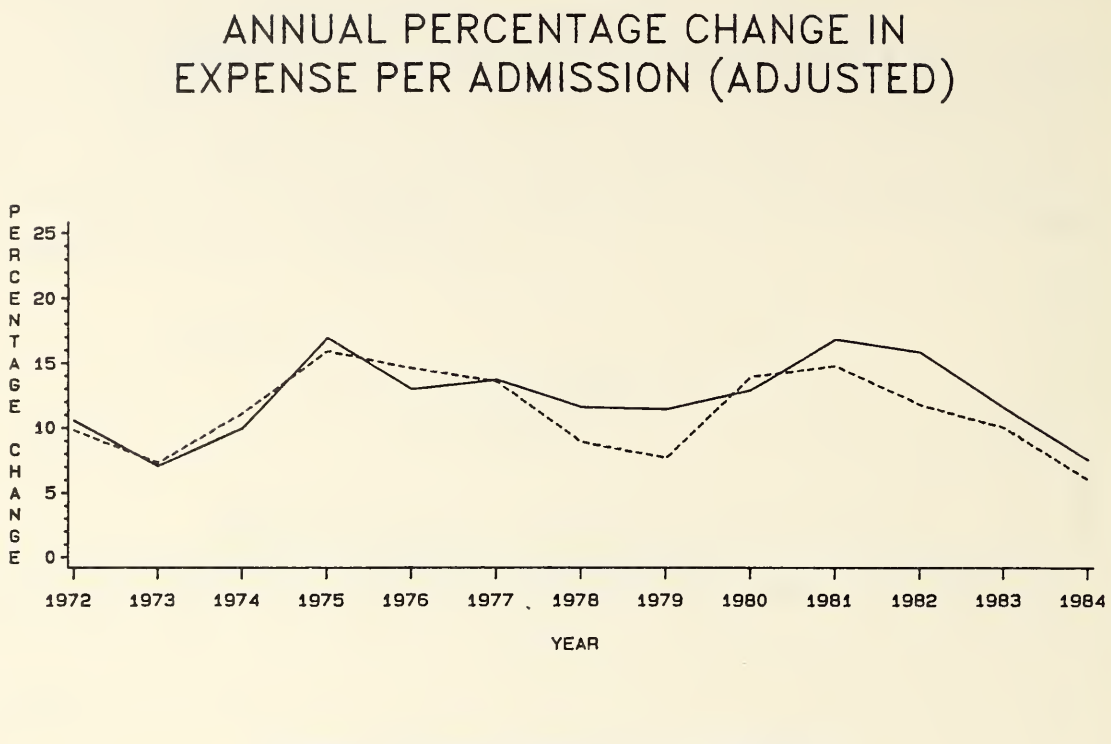


FIGURE 5.

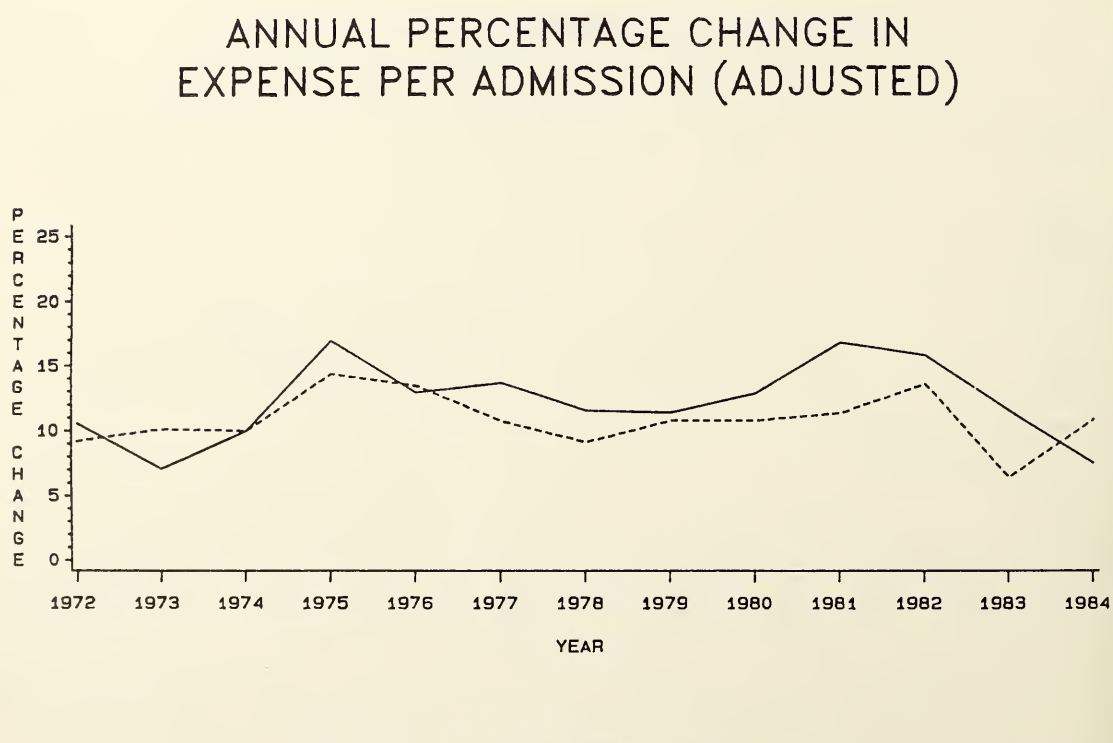


FIGURE 6.

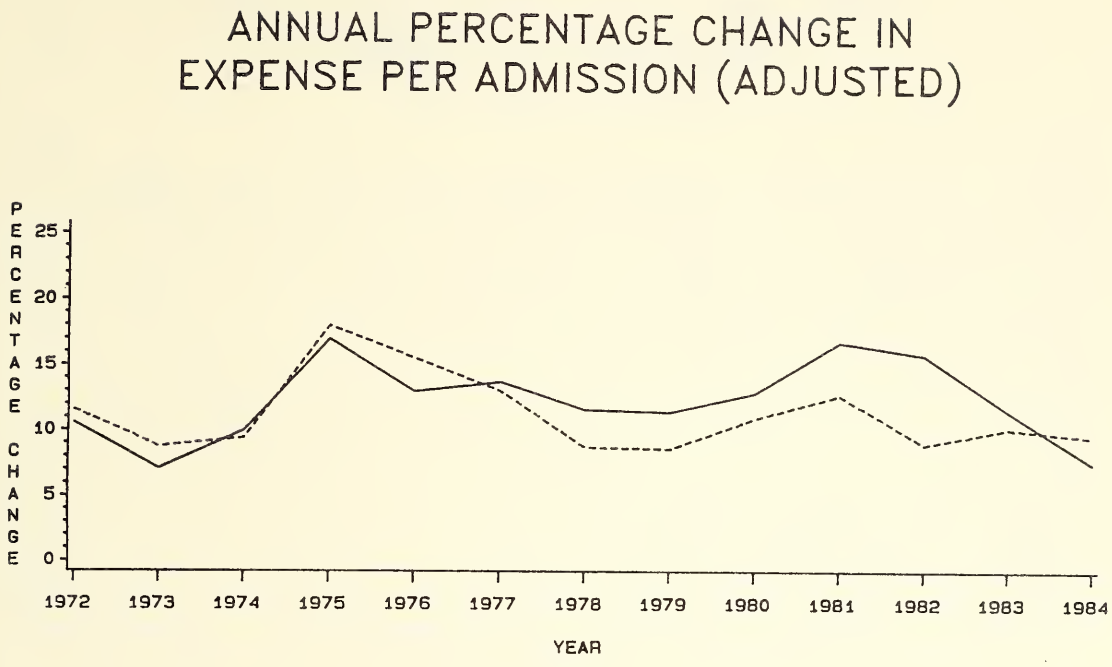


FIGURE 7.

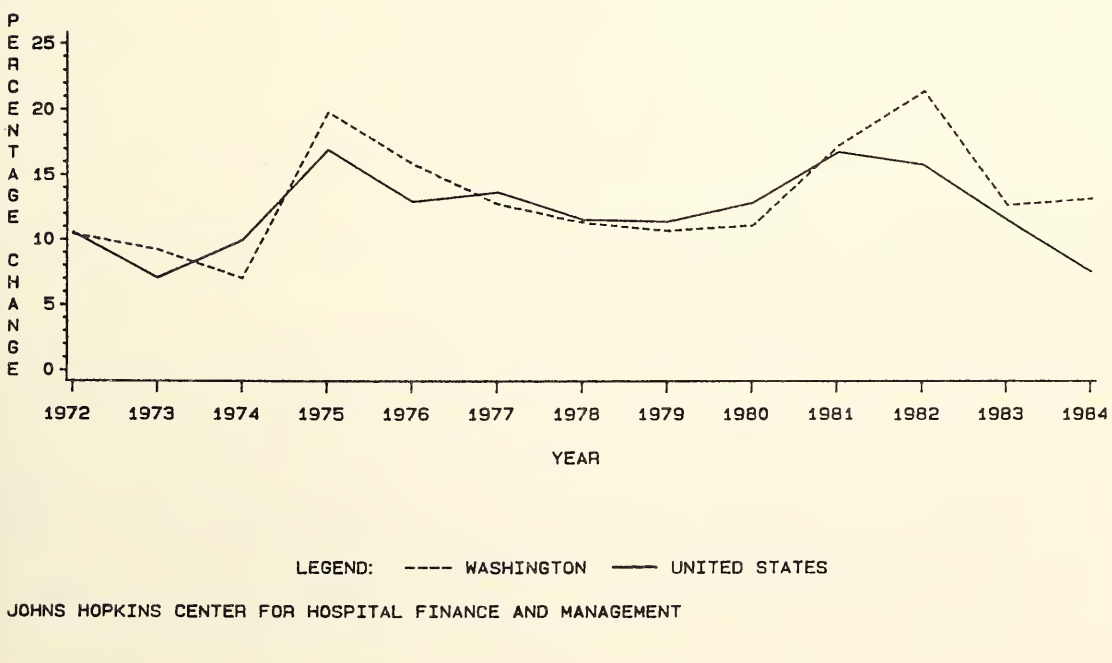
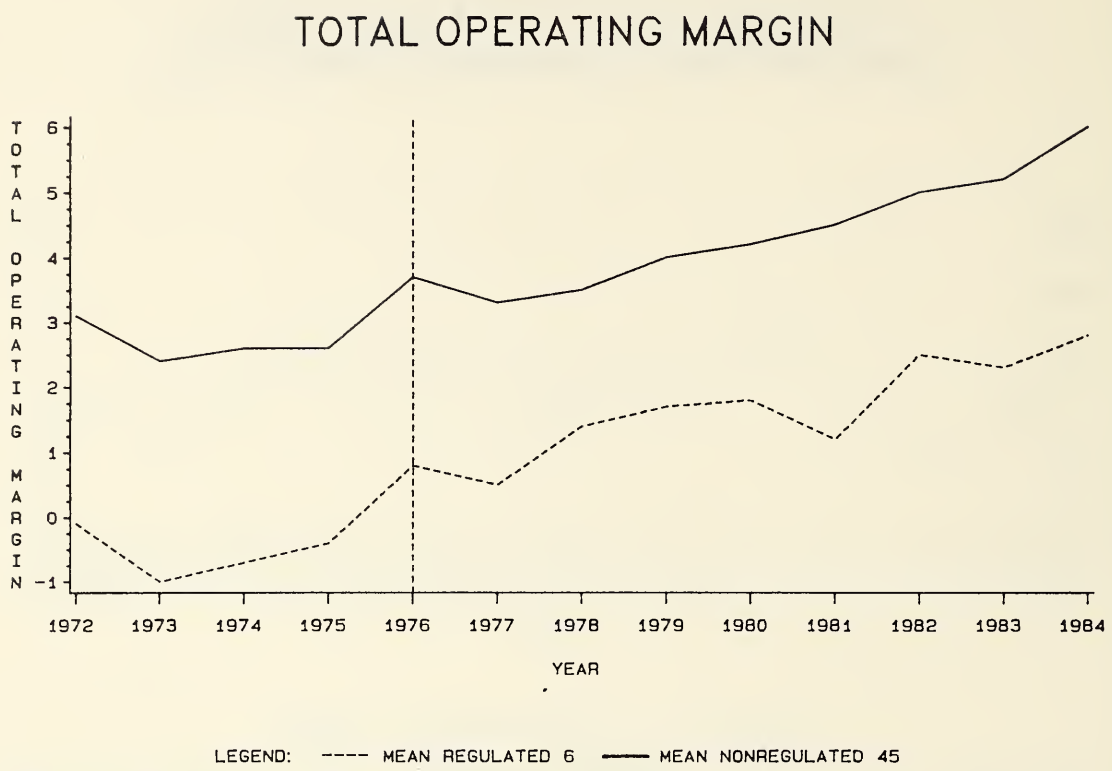


FIGURE 8.


TOTAL OPERATING MARGIN
TOTAL OPERATING MARGIN
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LEGEND: ---- MEAN REGULATED 6 —— MEAN NONREGULATED 45
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Liver Transplantation in Massachusetts: Public Policymaking as Morality Play*

Clark C. Havighurst**
Nancy M. P. King***

In 1982, Jamie Fiske, the infant daughter of Mr. and Mrs. Charles Fiske of Massachusetts, was dying of congenital liver disease. Her death was imminent, except for the possibility that a liver transplant—a difficult, risky, and extremely costly surgical procedure considered by many authorities still to be experimental—could prolong her life, for months or years, under a lifetime regimen of drugs to prevent her body's natural rejection of the foreign tissue. No surgeons or hospitals in Massachusetts performed liver transplants at the time. Moreover, the Massachusetts Blue Cross and Blue Shield plans (MBCBS), the family's health insurers, advised the Fiskes that such an experimental procedure would not be covered under their policy.[1] Thus begins the complex morality play, "Liver Transplantation in Massachusetts."

In addition to the Fiskes, the players in this drama include: two state-appointed commissions, composed of prominent citizen-experts; the state Department of Public Health; the state Medicaid program; MBCBS and Blue Shield's president, John Larkin Thompson; and, as a kind of Greek chorus, the omnipresent media. The role of "identified life"[2] is

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[1]Because the Fiskes had initially been guaranteed coverage for the transplant by an MBCBS employee, the Blues eventually agreed to pay for Jamie's treatment even though the procedure was technically excluded from plan coverage.

[2]The special function of characters like Jamie—endangered individuals whose jeopardy could be relieved by heroic or extraordinary governmental action—in dramas of this kind has been observed by numerous critics. Interestingly, many if not most of these critics have been Harvard professors and citizens of Massachusetts. *See, e.g.,* Fried, *The Value of Life*, 88 Harv. L. Rev. 1415 (1969); Fuller, *The Case of the Speluncean Explorers*, 62 Harv. L. Rev. 616, 623 (1949); Schelling, *The Life You Save May Be Your Own*,

played by Jamie Fiske, whose plight precipitated a dramatic medical rescue and who has so far lived as happily ever after as her circumstances permit. Absent from the play, even as off-stage voices like the unborn children in *Die Frau ohne Schatten*,[3] are the "statistical lives" that policymakers reputedly find easier to ignore than identified lives in allocating public resources.[4]

The action takes place under the full glare of publicity. The setting, the Commonwealth of Massachusetts between 1982 and 1985, features a highly regulated health care system built on assumptions that were common in the 1960's and 1970's but that are not universally embraced in the United States today. To understand the plot of this drama, it is helpful to recognize that the political ethos of Massachusetts envisions a true health care "system" governed centrally in accordance with explicit public choices. Thus, although Jamie Fiske's fate was not directly in the hands of the Commonwealth, the state government seemed to view itself as responsible for seeing that nothing so publicly heart-rending could happen again.

This review of the Massachusetts experience with liver transplantation treats it as a case study of how a centrally controlled health care system faces difficult choices concerning health care and health care technology. Despite its many special features, the problem of liver transplantation is not *sui generis*. Health care abounds with similar questions concerning marginal trade-offs between benefits and costs. Although few of them are as visible or as fraught with the characteristics of "tragic choices"[5] as organ transplantation, the basic dilemma of whether to spend scarce resources to achieve a particular health benefit of possibly less than commensurate value is always the same. The choice of decisionmaking mechanisms, public or private, through which to address these inescapable trade-offs has been the fundamental problem of health policy in the United States.[6]

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in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS 127 (S. Chase ed. 1968); Zeckhauser, *Procedures for Valuing Lives*, 23 PUB. POL'Y 419, 447, 458-59 (1975); *see also* Evans, *Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions*, pts. 1 & 2, 249 J. A.M.A. 2047, 2208 (1983); Friedman, *Rationing and the Identified Life*, HOSPS., May 16, 1984, at 65; *infra* text accompanying notes 37-43.

[3]A well-known operatic fantasy by Richard Strauss and Hugo von Hofmannsthal.

[4]*See generally* Havighurst, Blumstein, & Bovbjerg, *Strategies in Underwriting the Costs of Catastrophic Disease*, LAW & CONTEMP. PROBS., Autumn 1976, at 122, 140-45; *see also supra* references cited note 2 and *infra* text accompanying notes 37-43.

[5]The term is Guido Calabresi's. *See generally* G. CALABRESI & P. BOBBITT, TRAGIC CHOICES (1978). Tragic choices arise in situations where no decision can be satisfying because any choice necessarily sacrifices one or more irreconcilable fundamental values. Scarcity is the fundamental condition that necessitates such choices. Not all choices are tragic, of course, and markets are usually tolerated to allocate mundane goods and services. Where the opportunity cost of a particular choice includes a highly visible possibility of a lost life or other personal tragedy, however, its potentially tragic character appears.

[6]*See generally* Havighurst & Blumstein, *Coping with Quality/Cost Trade-offs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6, 9-45 (1975).

American society as a whole is somewhat less committed than Massachusetts to centralized decisionmaking on questions of what health services should be provided. Indeed, although the enactment of Medicare and Medicaid in 1965 started a seemingly inexorable movement toward such centralization of authority in government hands, recent years have seen a distinct movement in the opposite direction, particularly in federal policy.[7] Despite the promise of this new policy and some signs that hopes for it are being rewarded, it is still not clear that private choices can effectively ration expensive, potentially lifesaving therapies or that such rationing, if effective, would be acceptable politically. Many believe that effective and acceptable rationing can be achieved only by having government assume direct or indirect control of technology and health care spending. Although the Massachusetts experience with liver transplants provides no answers to these policy questions, it yields some insights into the relative merits of both approaches.[8]

I. Act One

Jamie Fiske's father successfully pleaded her need for a transplantable organ (and financial assistance) before the entire country, leading to a successful transplant at the University of Minnesota in November 1982. As a direct result of Jamie's case and the publicity it attracted, several things happened back home in Massachusetts. Several hospitals in Boston, all of them nationally prominent research and tertiary care centers, began expressing an interest in undertaking liver transplants. Other candidates for transplant surgery began appearing and pressing for financial support for the expensive lifesaving therapy. Such developments immediately focused attention and pressure on state government, because Massachusetts hospitals were not free to offer the service without a "determination of need" (DON) by state health planners[9] and because the state Medicaid program was one of the payers being asked to cover the cost. In addition, although MBCBS were private entities, they were finding it difficult both on medical grounds and as a public relations matter to insist that liver transplantation was still "experimental" and therefore not covered by their insurance contracts. MBCBS were hopeful that the state would

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[7]*See generally* Market Reforms in Health Care (J. Meyer ed. 1983); Havighurst, *The Changing Locus of Decisionmaking in the Health Care Sector*, 11 J. Health Pol. Pol'y & L. 697 (1986).

[8]For other studies providing insight on technology assessment, rationing, and tragic choices in different health care settings, see generally H. Aaron & W. Schwartz, The Painful Prescription (1984) (describing the rationing of health care in the United Kingdom); Institute of Medicine, National Academy of Sciences, Assessing Medical Technologies (1985); Minnesota Coalition on Health Care Costs, The Price of Life: Ethics and Economics (Dec. 1984) [hereinafter Minnesota Coalition Report]; Office of Technology Assessment, Medical Technology Under Proposals to Increase Competition in Health Care (1982).

[9]Mass. Gen. Laws Ann. ch. 111, § 25B (West 1977).

take the heat either for denying the service or for authorizing it and the higher insurance premiums needed to pay for it. Under these circumstances, the Commonwealth government did the predictable thing—it appointed a commission.[10]

A. The Fineberg Task Force and Report

The Liver Transplantation Task Force (LTTF), which was created in December 1982, was charged by the Commissioner of Public Health with the task of discussing several issues, including the question, "Should this type of program and procedures be encouraged or permitted?"[11] Notably, this charge directly raised the fundamental question of whether the state should allow livers to be transplanted at all. It envisioned a range of possible postures for the state, from prohibition to neutrality to active encouragement. Although outright suppression of either research on a new technology or use of a technology once developed would, in practice, raise serious political and legal questions, the LTTF was nevertheless asked to recommend what state policy ought to be.

The LTTF's report, known as the Fineberg Report,[12] was issued in May 1983. It described liver transplantation as

> a technically feasible, extreme and expensive procedure, demonstrably capable of extending the lives of some patients near death, and with substantial uncertainties about optimal selection of patients, appropriate criteria for excluding other patients, optimal matching of donor organs and recipients, effectiveness under conditions of more widespread use, and the extent of benefits and costs.[13]

The report recommended that liver transplants in Massachusetts be limited to one adult and one pediatric program with extensive data to be gathered from these programs in order to clarify the numerous "uncertainties" it had identified.[14] The LTTF viewed both this data gathering and systematic evaluation of the procedure as vitally important.

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[10]This commission was the Liver Transplantation Task Force (LTTF), which was created in December 1982.

[11]Letter from Alfred L. Frechette, Commissioner of Public Health, Commonwealth of Massachusetts, to Harvey Fineberg, Harvard School of Public Health (Dec. 27, 1982) *reprinted in* FINAL REPORT OF THE TASK FORCE ON LIVER TRANSPLANTATION IN MASSACHUSETTS B1-B2 (May 1983).

[12]FINAL REPORT OF THE TASK FORCE ON LIVER TRANSPLANTATION IN MASSACHUSETTS (May 1983) [hereinafter FINEBERG REPORT] (known as the Fineberg Report after the chairman of the LTTF, Harvey Fineberg of the Harvard School of Public Health).

[13]*Id.* at 34.

[14]*Id.* at 36, 40-41. The report also recommended that liver transplantation be initiated under a special one-year DON exemption, so that the data gathered by the new programs could be evaluated before a final DON determination was made. *Id.* at 39-40. In a

In addition, the Fineberg Report provided extensive cost estimates on liver transplantation, derived largely from data supplied by MBCBS.[15] It identified eleven cost components, ranging from preoperative expenses, surgery, and follow-up to the costs of complications, including rehospitalization and additional transplants.[16] It concluded by estimating that the average cost per Massachusetts patient surviving one year after the transplant would be $238,800.[17] The report candidly acknowledged that some of its assumptions may have reduced the reliability of this estimate, noting that it took hospital charges to reflect true resource costs and ignored both indirect economic effects and "potential savings attributable to averted medical expenses" incurred in caring for a dying patient.[18] The report's completeness and candor on these points were unprecedented; they serve to highlight the shortcomings of other prominent studies and the great need for better data gathering.[19]

The LTTF's average total cost figure obscures the possibility that the marginal or incremental cost of a transplant may be considerably less. Based on the observation that transplantation could be undertaken in Massachusetts hospitals without adding equipment or personnel, the LTTF concluded that hospitals undertaking transplantation should be required to do so within their respective current cost ceilings under Massachusetts' system for regulating hospital revenues.[20] Under this recommendation, a hospital could receive no additional funds by virtue of adding a liver transplantation program and would thus have to finance its involvement from any surpluses it might earn or by economizing on (or terminating) the provision of other services. It appears that the LTTF judged liver transplantation to have so little proven value to date that new public or private outlays for it were not warranted. A payment restriction was one of several methods by which the LTTF hoped to achieve a "controlled dissemination of liver transplantation in Massachusetts" until more data on its efficacy, cost, and desirability were collected.[21]

Although this decisive call for caution seemed to stem from strong reservations about the value of the new technology, the Fineberg Report stopped short of addressing the most fundamental question raised in its charge. Admitting great discomfort in addressing the question of whether liver transplantation should take place at all, the LTTF passed the buck.

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thoughtful discussion establishing the need for this data gathering, the report described liver transplantation as being somewhere "on the continuum between 'experimental' and 'established.' " *Id.* at 8.

[15] *Id.* at 25.

[16] *Id.* at 27.

[17] *Id.*

[18] *Id.* at 29.

[19] *Id.* at 30.

[20] *Id.* at 39-40.

[21] *Id.* at 35.

Declaring itself "not legitimately constituted to render these views on behalf of society,"[22] the LTTF asked the Commissioner of Public Health to "appoint a broadly representative advisory body to consider the difficult value judgments about whether society can and should support liver transplantation and to what degree."[23] Hidden in this response, it should be noted, is an affirmation of the assumption that a single choice for "society" as a whole is necessary and appropriate and that this choice should be made by a committee in the first instance and ultimately by political processes. By recasting the question to focus on whether society should "support" transplantation, the LTTF seemed to eliminate the possibility that transplantation would be expressly forbidden. It is also possible, however, that the LTTF simply recognized that the regulatory blanket covering Massachusetts hospitals was so stifling that a decision not to "support" transplantation was tantamount to prohibiting it.

B. The Regulatory Setting

The specific occasion for creating the LTTF was an application by New England Deaconness Hospital to the Department of Public Health for an exemption from state DON requirements that would allow a small number of liver transplants in 1983.[24] On further inquiry, the Department found that the Massachusetts General Hospital, Children's Hospital, and the New England Medical Center were also prepared to perform liver transplants.[25] It was hardly surprising that Boston's internationally prominent research hospitals were eager to perform liver transplants after the publicity given to Jamie Fiske's ordeal.

Like those of other states, Massachusetts' certificate-of-need program (known as DON) makes capital expenditures and substantial changes of service subject to approval by state authorities.[26] Such regulatory programs, the adoption of which was at one time required by federal law,[27] were established in an effort to curb the proliferation and expansion of health care facilities so that growth would correspond to officially pro-

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[22]*Id.* at 31. The LTTF's reservations about its competency were based on the fact that it was composed predominantly of scientists.

[23]*Id.* at 42.

[24]*See* Letter, *supra* note 11. Several interviews confirmed the identity of the institution in question.

[25]These four hospitals supplied the LTTF with much of its information about the feasibility of liver transplantation in Massachusetts. *See* FINEBERG REPORT, *supra* note 12, at app. D.

[26]MASS. GEN. LAWS ANN. ch. 111, § 25B (West 1977).

[27]The Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 93 Stat. 606 (1974) (codified in scattered sections of 42 U.S.C.), made the availability of certain federal funds conditional on the enactment of a certificate-of-need program

jected needs.[28] The Massachusetts DON statute and regulations give especially broad authority to the Department of Public Health to determine whether a "substantial change in services" is needed,[29] and it was apparently conceded that a liver transplantation program needed state approval under this provision. The immediate reason for commissioning the Fineberg Report was to assist the Department in the DON process.[30] Without affirmative action by the Commonwealth, Boston's research hospitals would be barred from performing liver transplantation.

For interested hospitals, getting a DON was only the first regulatory hurdle. Massachusetts places a ceiling on hospital expenditures through its "all-payer" Maximum Allowable Cost (MAC) system.[31] Under this system of revenue limits, each acute care hospital's annual operating budget ceiling is determined in advance by the state, and the hospital is then permitted to collect revenues necessary to cover its anticipated needs from Medicare, Blue Cross, and private insurers, roughly in proportion to the number of beneficiaries treated.[32] Instituted in 1982, the MAC program assures each hospital prospectively that it will receive payments reflecting its actual 1981 costs plus adjustments for inflation, exceptions, and certain other factors.[33] The provision for exceptions permits a hospital to seek additional revenues to cover the anticipated costs of approved new services, such as liver transplants, and capital and operating expenses associated with other DON's.[34]

Naturally, any hospital receiving a DON to begin performing liver transplants would also wish to receive payment for them under a MAC exception. Under the Fineberg Report's recommendation, however, the

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meeting certain standards. The federal compulsion has recently been relaxed. *See Deregulation Is Growing Trend for State CON Programs*, ALPHA CENTERPIECE, Feb. 1986, at 1. Pending legislation would make state participation voluntary. *See Health Planning Bill Passed*, 44 CONG. Q. WEEKLY REP. 268 (1986).

[28]On the policy underlying certificate-of-need laws, see generally C. HAVIGHURST, DEREGULATING THE HEALTH CARE INDUSTRY: PLANNING FOR COMPETITION 26-30, 54-63 (1982); Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83, 84-97; Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need,"* 59 VA. L. REV. 1143, 1148-69 (1973).

[29]MASS. GEN. LAWS ANN. ch. 111, § 25B (West 1977); MASS. REGS. CODE 105, § 100.020 (1977).

[30]FINEBERG REPORT, *supra* note 12, at app. B.

[31]The MAC system was put into place by chapter 372 of the Massachusetts Acts of 1982. *See* MASS. GEN. LAWS ANN. ch. 6A (West Supp. 1985). It established a prospective payment system for Medicaid and private insurers, modeling the approach after a Blue Cross hospital payment contract already in use. A federal waiver made the state's payment system binding on the Medicare program. *Id.*

[32]*See* MASS. GEN. LAWS ANN. ch. 6A, §§ 50-56 (West Supp. 1985).

[33]*Id.*

[34]*Id.*

exception would not be granted and the hospital would have to finance the service out of savings elsewhere. Under these circumstances, a transplant candidate with an insurer willing to pay for the procedure might not find a Massachusetts hospital willing to provide it, because any hospital revenue from treating that patient would have to be offset by reduced revenue from treating others.[35] On the other hand, a MAC exception would allow the hospital to cover the costs of transplants by cost shifting, increasing its charges to the various payers in order to pay for transplants needed by patients lacking adequate insurance.[36]

Under these regulatory circumstances, the willingness or unwillingness of payers to pay for, or of patients to buy coverage for, such procedures would have little or no effect on whether transplants would be undertaken. This decision was essentially the state's, and if the state decided to authorize the service, the public would pay for it one way or another. But this payment would not necessarily be through the usual method of openly levying taxes and explicitly appropriating funds for worthy public projects. The Massachusetts philosophy, with which no one seems to have quarreled throughout this episode, is apparently that the state alone, through the DON-MAC process, should finally dictate such matters. The state's potential role in frustrating transactions between a willing buyer and a willing seller was not commented upon. As will be seen, the state was comfortable with—though perhaps not entirely comfortable in—its role as giver or withholder of lifesaving medical treatment.

C. The Political Scene

It is a widely noted fact of our political life that when an individual human life is placed in visible, media-covered jeopardy, a tug on the public heart strings loosens governmental purse strings, causing expenditures to save that "identified life" which far exceed what government is willing to spend to save an otherwise comparable "statistical life."[37] This phenomenon of our media-driven democracy can be viewed in contrasting ways. It is either, on the one hand, an inexcusable pandering to public passions by public officials freely using public funds to establish that they are compassionate and deserve re-election or, on the other

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[35]Freezing the resources available to an institution places responsibility for allocating those resources on the institution and its physicians. Decisions may not reflect the public's priorities because internal institutional politics allow economic interests and professional values to enter the picture. *See* Harris, *Regulation and Internal Controls in Hospitals*, 55 BULL. N.Y. ACAD. MED. 88 (1979).

[36]The MAC system effectively breaks most of the links between the private insurance coverage that individuals buy and the care they receive. Hospitals are free to provide any of the myriad of services authorized by their DON and to tax the cost proportionately to all payers, up to the MAC limit. *See supra* note 35.

[37]*See supra* notes 2, 4.

hand, a healthy and reassuring affirmation that the community prizes each individual and is not coldly calculating when human life is at stake. Although such seemingly inefficient expenditures may be defensible because they give the community a chance to feel good about itself, it is also possible that they cultivate false impressions and divert attention and resources away from unfulfilled obligations.

Jamie Fiske's story had poignant consequences nationwide and illustrated the dilemmas that government faces in allocating public resources to health care in a political environment that demands concern for a handful of identified lives. Following Jamie's transplant, public and private financing mechanisms across the country faced strong public pressure to cover the costs of the procedure for other individual victims, frequently children.[38] The pressure was particularly acute for state Medicaid programs; a number of governors and legislatures responded by issuing ad hoc directives to finance highly publicized cases with state funds. In Missouri, for example, the legislature specifically authorized an exceptional payment on behalf of a 16-year-old girl, only to reverse itself the following week when two things happened: additional candidates appeared, demonstrating that one costly symbolic act would not be enough to satisfy the media, and perhaps consequentially, such private legislation was found to violate the state constitution.[39]

Nowhere was the political pressure on a Medicaid program greater than in Massachusetts—the home of Jamie Fiske, as well as a major center for biomedical research and a state that had gone very far in accepting political responsibility for the operation of the health care enterprise. Massachusetts Medicaid declared liver transplants reimburseable for eligible persons in the summer of 1983. From then until January 1984, Massachusetts was in the anomalous position of guaranteeing to the very poor an extremely costly medical procedure that was not available to middle-class MBCBS subscribers. Thus, taxpayers were forced to buy for others transplants which they had not yet chosen to purchase for themselves through insurance. Although MBCBS was also under pressure, it was able as a private entity to hold out longer. This experience seems to confirm that elected officials and programs accountable to them—even more than private nonprofit organizations that strive to be perceived as benign dispensers of good things—do indeed seize opportunities to demonstrate their compassion by spending scarce public funds irrationally.[40]

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[38]*See, e.g.*, Friedman & Richards, *Life and Death in a Policy Vacuum*, HOSPS., May 16, 1984, at 79; Wessell, *Medical Quandary: Transplants Increase, and So Do Disputes Over Who Pays Bills*, Wall St. J., Apr. 12, 1984, at 1, col. 1; Rust, *Transplant Successes Stir Debate on Coverage*, Am. Med. News, Oct. 21, 1983, at 1.

[39]Friedman & Richards, *supra* note 38, at 80.

[40]One report asserts that this pattern is not universal, and suggests that public insurers are on the whole reluctant to cover expensive new technologies. Evans, *Transplant Coverage:*

Undoubtedly, Medicaid dollars allocated to transplants could have been put to better use in saving statistical lives or purchasing "quality-adjusted life years."[41] In California, the point was illustrated most tellingly: the legislative decision to pay for liver transplantation came at the same time that the legislature decided to terminate state support for its medically indigent population, those who cannot afford insurance for their own health care but are not deemed poor enough to warrant public assistance.[42] The eagerness of public officials to gain credit for their humanitarianism, especially when someone else's money was at stake, was revealed even in the White House, which made a number of dramatic appeals to state governments and private payers on behalf of particular individuals.[43] These scenes of elected representatives crowding onto the stage of this morality play left to the audience's imagination the effects of government policies on those who lacked the limelight.[44]

D. The Private Sector: MBCBS

Just as the public sector felt pressure to finance transplants for identified patients, private insurers all over the country, particularly Blue Cross plans, found themselves making difficult case-by-case decisions in full view of the media. MBCBS's particular problem in this regard was

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A Public Policy Dilemma, BUS. & HEALTH, Apr. 1986, at 5. As the Missouri experience (*see supra* text accompanying note 39) suggests, government's largess will stop when the costs to policymakers exceed the political benefits of being associated with a lifesaving effort.

[41]Expanding Medicaid eligibility and coverage of preventive services would be obvious strategies. *See, e.g.*, PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECURING ACCESS TO HEALTH CARE: THE ETHICAL IMPLICATIONS OF DIFFERENCES IN THE AVAILABILITY OF HEATH SERVICES, 19-20, 59-65, 79-90 (1983) [hereinafter PRESIDENT'S COMMISSION REPORT] (discussing what ought to be encompassed by "an adequate level of health care" available to all citizens and highlighting current problems in health services delivery). On the use of "quality-adjusted life years" as a way of assigning priorities to public investments in health and safety, see, e.g., Zeckhauser & Shepard, *Where Now for Saving Lives?*, LAW & CONTEMP. PROBS., Autumn 1976, at 5, 11-15.

[42]Wessell, *supra* note 38.

[43]*Id.*; *see also* Iglehart, *Transplantation: The Problem of Limited Resources*, 309 N. ENG. J. MED. 123, 126-27 (1983); Meyer, *Transplant Funding: A Controversial New Area*, Washington Post, Sept. 12, 1984, at C3, col. 1.

[44]In yet another demonstration of elected officials' felt need to "do something" to respond to media attention to the transplantation issue and to get media attention for themselves, the Massachusetts legislature, in late 1983, added a check-off box to the state's income tax returns so that taxpayers could direct that a portion of any tax refund go into an organ transplantation fund. In 1985, when the checkoff first appeared on tax forms, some 37,000 taxpayers contributed approximately $187,000 to the fund, which will probably be used primarily to help pay for cyclosporin and other follow-up care for transplant recipients. Interview with Joan Gorga, Dept. of Public Health, Boston (July 1985).

not solved by the continued failure of Massachusetts regulators to authorize transplants, because insureds could still request treatment out of state. For this reason, MBCBS did not oppose the effort by local hospitals to get DON approval for transplantation. Indeed, MBCBS took the view that if they were going to have to pay for transplants eventually, it would be better to pay for in-state procedures.[45] They anticipated that the MAC system would control the incremental cost and that the DON system would limit the number of facilities.[46] Together these regulatory programs might restrict the capacity and the incentives of the system to perform more than a few procedures.

For the time being, however, MBCBS were reluctant to accept responsibility for paying for liver transplants anywhere. According to MBCBS officials, public pressure to pay for liver transplants in 1982 and 1983 was enormous. Although they did not wish to be perceived as denying potentially beneficial care, however costly, to any insured,[47] the plans were also hesitant to waive the contractual limitation under which they were obligated to pay only for generally accepted medical procedures. One reason for this attitude was recognition of the financial cost which transplants would impose on them immediately and which would have to be built into future premiums charged to customers already grumbling about high insurance costs.[48]

Another explanation, however, had to do with MBCBS's view of their precise role in the Massachusetts system. MBCBS complained that they were not getting clear signals from their usual sources. On the one hand, there were the pressures from the media and the example set by the Medicaid program. On the other hand, the health care system's central decisionmakers were not speaking with one authoritative voice.[49] For example, in 1982 and 1983, although liver transplants were gaining favor, MBCBS's medical advisors could not reasonably declare liver transplantation to be accepted therapy covered by their policies because any reasonable chance of a procedure's success depended upon use of a drug, cyclosporin A, which the U.S. Food and Drug Administration (FDA) considered experimental until September 1983.[50]

Apparently wedded to a vision of themselves as mere financing intermediaries bound to give effect to any doctor's prescription made

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[45]Interviews with Douglas Dickson, Ombudsman, and James Young, M.D., Medical Director, Massachusetts Blue Cross (July 15, 1985); *see also* Rust, *supra* note 38, at 16.

[46]Dickson and Young interviews, *supra* note 45.

[47]*Id.*

[48]Wessell, *supra* note 38.

[49]Rust, *supra* note 38. The termination of the National Center for Health Care Technology in a 1981 funding cut left MBCBS and other third-party payers without the prospect of an authoritative governmental opinion on which to base their payment decisions.

[50]Food & Drug Administration, U.S. Dep't of Health & Human Services, HHS News, Pub. No. 83-19 (Sept. 2, 1983).

according to policies centrally determined by professional or governmental decisionmakers,[51] MBCBS preferred to rest coverage decisions on the actions of public regulatory agencies such as the FDA. They thus resisted any suggestion that they should embark on independent assessments of medical treatments, either paying for something officially deemed experimental or refusing on benefit/cost grounds to pay for something that enjoyed professional and governmental approval. As nonprofit corporations together constituting the dominant health insurer in Massachusetts, MBCBS were dependent on the public's perception of them as a benign source of financial assistance in meeting officially recognized medical needs. The Blues were beginning, however, to see the high cost and difficulties of marketing themselves in this way.

In mid-1983, MBCBS's arguments for not paying for liver transplants began to collapse. In May, the Fineberg Report called liver transplantation "clinically justifiable,"[52] and in June, a National Institutes of Health consensus conference stated that "liver transplantation offers an alternative therapeutic approach which may prolong life in some patients."[53] When these lukewarm semi-official endorsements of liver transplantation were combined with media attention to the plight of transplant candidates and the relative willingness of other insurers and Medicaid to pay for liver transplants, they seemed to leave MBCBS with no choice. MBCBS had to discover some way around their own guidelines or be perceived as denying treatment solely because of the procedure's high cost. The solution that MBCBS hit upon was to offer their subscribers a Transplant Insurance Program, called "TIP."[54] By this means, they hoped to bridge the gap until the FDA would approve cyclosporin A, which would allow MBCBS, consistent with their principles, to build transplants into their basic coverage and rates.

TIP was a separate, optional rider offered to all employment groups or "accounts" at a cost of 55 cents per individual or $2 per family per month. TIP offered full coverage for heart, heart-lung, and liver transplants, beginning five days before the procedure and continuing for twelve months thereafter.[55] If an account chose to purchase TIP, it would be mandatory rather than optional for the account's insureds or "mem-

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[51]For complex reasons, private health insurers have long denied responsibility for influencing providers' treatment decisions, relying instead on professional or governmental decisionmakers to establish what services should be paid for. *See* Havighurst, *Explaining the Questionable Cost-Containment Record of Commercial Health Insurers*, in THE POLITICAL ECONOMY OF HEALTH CARE (H. Frech ed. to be published).

[52]FINEBERG REPORT, *supra* note 12, at 2.

[53]NATIONAL INSTITUTES OF HEALTH, CONSENSUS DEVELOPMENT CONFERENCE SUMMARY, LIVER TRANSPLANTATION (1983).

[54]*See* Rust, *supra* note 38, at 16-17.

[55]Blue Cross & Blue Shield of Mass., "Special Announcement: New Transplant Insurance Plan" (Sept. 1983) [hereinafter Special Announcement] (mailing to accounts).

bers." Before offering TIP, Blue Cross conducted several opinion surveys to determine whether the public pressure they were feeling would actually translate into individual choices to purchase transplant insurance. These surveys indicated considerable desire for such insurance on the part of surveyed individuals and families.[56] However, the response to TIP itself differed significantly from the response to the surveys.

TIP was offered to MBCBS accounts in September 1983. Although John Larkin Thompson, president of Blue Shield, called TIP "the ultimate referendum on whether or not the public wants to pay for these operations,"[57] TIP was not offered directly to individual members because MBCBS feared the effects of adverse selection.[58] It was left to employers to act for their insured employees. Conceivably, publicity given to the transplant issue placed employers in a political position vis-a-vis their workers that was not dissimilar to that of MBCBS and Medicaid vis-a-vis the larger public. Not wanting to appear to economize at the expense of employees who might need a transplant, employers may have been more willing to buy TIP than the employees themselves would have been. On the other hand, employers might be reluctant to buy transplant coverage because its cost might be perceived as difficult to pass on to employees.

Each account was sent a special announcement explaining TIP, which stated, "The public has indicated its desire to have coverage for organ transplants."[59] The announcement was clear and complete, but gave accounts only about a month to make a decision whether to begin TIP coverage on November 1. It left them, however, the alternative of picking it up at their regular renewal period during the next calendar year.

The TIP "referendum" was never completed because MBCBS discontinued it as of February 1, 1984. Cyclosporin A had actually received FDA approval in September 1983,[60] and in January 1984, MBCBS's medical advisory committee finally recommended that liver, heart, and heart-lung transplants be considered medically accepted procedures. These developments allowed transplantation coverage to be extended to all accounts, with a premium increase roughly equal to the TIP premium.

In contrast to the results from MBCBS's preliminary surveys, TIP did not prove especially popular during its brief marketing. By the time it was discontinued, only 7400 of the 24,348 accounts to which it was offered had purchased the coverage, 7100 had refused it, and the rest

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[56]Dickson interview, *supra* note 47.

[57]Rust, *supra* note 38.

[58]Dickson interview, *supra* note 47; Interview with Dorris C. Commander, Underwriting Manager, Blue Cross of Massachusetts (July 1985).

[59]Special Announcement, *supra* note 55.

[60]Food & Drug Administration, U.S. Dep't of Health & Human Services, HHS News, Pub. No. 83-19 (Sept. 2, 1983).

—over 9800—had not responded.[61] Even the Massachusetts Commissioner of Insurance, who had statutory responsibility to act as the account decisionmaker for MBCBS's 120,000 nongroup subscribers (including a special group of low-income individually insured), had failed to make a decision regarding TIP before it was mooted.[62] There are many possible explanations for the modest response rate. Some accounts may have intended to pick up TIP when they next renewed their coverage. According to MBCBS, however, financial considerations probably loomed largest in accounts' decisionmaking. In addition, some accounts, particularly large ones based in more than one state, may have preferred to pay for transplantation in different ways so as to be able to offer uniform coverage to employees in all states. One employer, Honeywell, wanted the opportunity to approve the transplanting facility.[63] MBCBS were much more interested in seeing that someone other than themselves, preferably the state through DON, would be responsible for approving facilities and quality control.[64]

At MBCBS, there was little surprise at TIP's poor showing, and the perceived reason for it was TIP's cost. Yet no thought was ever given to making a point of the public's apparent indifference to transplant insurance once an actuarially fair price tag was attached. Perhaps MBCBS saw no difference from a public relations standpoint between denying transplants on the ground that the procedure was experimental and telling an individual that because his employer had rejected the TIP offer, he could not have a lifesaving procedure that the plan was providing for others.

In any case, MBCBS made no real effort to examine and ponder the significance of the TIP experiment. Indeed, they were quite happy to extend their regular coverage to handle transplants. TIP had been complicated and cumbersome. Because it constituted a separate insurance program with a separate pool of funds, TIP required a lot of tracking to separate costs attributable to the transplant from ordinary medical costs. This tracking difficulty led, in part, to the "five-days-before, twelve-months-after" policy under which all medical costs incurred within that period were deemed attributable to the transplant. Both this policy and, later, the demise of TIP sacrificed Blue Cross's ability to extract easily any data on transplants. All transplant data now go into the files with every other medical procedure and, as such, are entered per hospitalization rather than per individual insured; cumulative information

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[61]Friedman & Richards, *supra* note 38, at 79.

[62]Dickson interview, *supra* note 47.

[63]On Honeywell's transplant coverage, see MINNESOTA COALITION REPORT, *supra* note 9, at 48; Utah Health Cost Management Foundation, *Honeywell's Transplant Coverage Stresses Cost Containment*, HEALTH COST MANAGEMENT NEWS, May 1985, at 3.

[64]Young interview, *supra* note 47.

on rehospitalization, outpatient care costs, and related other costs are difficult to retrieve.[65]

Although apparently efficient, blending transplant coverage into a system geared only to paying claims and not to evaluating the costs and benefits of particular procedures may be a false economy. It is, however, a predictable feature of a health care system in which private insurers such as MBCBS perceive themselves merely as executing orders from the top. MBCBS throughout this episode seemed troubled only that they were unable to interpret the conflicting signals they received. Once transplants crossed the threshold of acceptability at the FDA, the NIH, the LTTF, and the DON agency, the Blues could go happily back to their usual business of forcing consumers to buy things that they have had no real opportunity to refuse.

E. Enter the Task Force on Organ Transplantation

The foregoing events left Massachusetts about to plunge into transplantation. Yet a number of problems still existed; these resulted primarily from the way in which the DON and MAC programs articulated. Simply granting a DON without increasing the MAC allowance, as recommended by the Fineberg Report, would give rise to the danger that hospitals, instead of cutting back on indisputable waste to finance transplants, would terminate other, more essential services, creating problems throughout the system. For example, a hospital closing a maternity service and using its MAC allowance to start transplants would leave its obstetrical patients to burden other hospitals, which could not be assured of increased MAC allowances to provide for these patients. In this way, the threat of sudden introduction of a costly new therapy revealed major flaws in the state's basic faith that hospitals' revenue needs could be predicted by a formula without creating major anomalies, windfalls, and unfairnesses.

The liver transplant challenge also revealed faults in the regulatory system. Simply granting a MAC exception on the theory that transplants had now become just another accepted therapy would mean losing the opportunity to ensure that the procedure was being used appropriately and that information on its safety, efficacy, and cost would be available for subsequent appraisal. The six-figure price tag for each procedure made it clear to everyone that letting the system treat liver transplants as it treats virtually everything else had significant fiscal implications. It of course occurred to no one to question publicly whether letting the system freely prescribe high volumes of other treatments with five-, four-, three-, and even two-figure price tags might also be socially inappropriate or wasteful. Thus, the basic belief that doctors and hopsital employ

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[65]Commander interview, *supra* note 58.

their limited resources rationally and in accordance with public objectives, a faith on which the entire regulatory system was built, was not challenged.[66] Instead, it was concluded only that the transplant issue, because it had met the public eye and could not politically be ignored, had to be addressed with greater particularity. Why the system could not be trusted here, when it was trusted to make virtually all other choices, was never made clear.

The need to control transplants specially loomed so large that another commission, the Task Force on Organ Transplantation (OTTF), was appointed. This new task force had a broader scope than the earlier one. It was charged with making policy for heart and heart-lung transplants as well as livers.[67] It was also asked to provide a social evaluation, not just a technical report. As the next act of our morality play will show, the OTTF was equal to the challenge to pronounce on the largest questions of public policy in health care.

II. Act Two

The OTTF was convened in October 1983, by the Commissioner of Public Health under the chairmanship of George Annas of the Boston University School of Public Health. It was charged "with the development of standards and processes for evaluating the use of organ transplantation."[68] The question expressly left unanswered by the Fineberg Report —whether transplantation should "be encouraged or [even] permitted"— was not even raised: "The work of the Task Force can be categorized in terms of the when, who, what and how of organ transplants."[69] Although the OTTF did hear testimony on the issue during its meetings,[70] the objections raised concerning whether to proceed with transplantation at all did not detain OTTF members long.[71] The political climate obviously precluded a firm stance against the new technology.

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[66]*See supra* notes 35 & 36.

[67]The OTTF's report was unclear why transplantation of bone marrow, kidneys, and other organs was not treated as well, but in stating that liver and heart transplants were "the [only] ones currently clamoring for wider introduction," the OTTF confirmed that its inquiry was shaped by politics, not by a desire to rationalize the provision of all expensive medical care. Report of the Massachusetts Task Force on Organ Transplantation (1984) [hereinafter OTTF Report].

[68]*Id.* at 3, 119 (app. A).

[69]*Id.* at 119 (app. A).

[70]Dr. Alan Sager of the Boston University School of Public Health argued before the OTTF that "all citizens of the Commonwealth should have equal access to all effective care now routinely available before the range of therapies is expanded." Testimony of Alan Sager (Oct. 31, 1983).

[71]Interview with George Annas, OTTF chairman (July 1985). The recent report of the National Task Force on Organ Transplantation, created by the National Organ Transplantation Act, Pub. L. No. 98-507, 98 Stat. 2339 (Oct. 19, 1984), does not address this issue, simply assuming that transplantation of all kinds should be covered by public and private

The OTTF's report, the recommendations of which were unanimous, was released in October 1984, although preliminary recommendations were released in January.

A. The OTTF's Recommendations

The OTTF's first recommendation advocates the introduction of liver and heart transplantation "in a controlled, phased manner that provides the opportunity for effective evaluation and review of its clinical, social, and economic aspects by a publicly-accountable body after an initial phase of 2-3 years of limited transplantation."[72] This position, which sounds and may well have been, under the circumstances, eminently reasonable, was almost certainly inevitable, given the political impossibility of saying "no" to transplants. The OTTF, like the LTTF before it,[73] was clearly seeking a middle ground that would accommodate the pressure to allow transplants but not open the door to unlimited spending on the new technology. The recommendation of a later evaluation was necessary to preserve the appearance that the procedure was still in an investigatory or probationary stage. As the Fineberg Report had noted, however, it is hard to stop a program once it has begun.[74]

The OTTF conveyed the impression that its unanimous conclusions were reached by rational planning, deep thinking by academic experts, and a collective social conscience. There is also the possibility, however, that it was simply compromising conflicting views, accommodating political pressures, and rationalizing the result. Although the charge that the OTTF's actions were in fact "political" might be taken as a criticism, many in Massachusetts would no doubt say that because the conclusions flowed from an open process and a representative body, the legitimacy and soundness of the result and of the values promoted are unchallengeable. Whether such faith in the politics of interest-group liberalism is warranted should be regarded as an open question, however,[75] and indeed it is one of the central questions inspiring this appraisal.

The OTTF's second recommendation elaborates on the first by emphasizing that transplantation should not be made "generally available" until after the recommended review by a "publicly-accountable body,"

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financing programs. U.S. DEP'T OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH SERVICE, HEALTH RESOURCES & SERVICES ADMIN., ORGAN TRANSPLANTATION: ISSUES AND RECOMMENDATIONS (April 1986). The Minnesota Coalition Report, noting the trend to coverage, recommended that it "should remain optional for group accounts;" no opinion was expressed on public plans' policies. MINNESOTA COALITION REPORT, *supra* note 8, at 47-48.

[72]OTTF REPORT, *supra* note 67, at 10.

[73]*See supra* text accompanying notes 14 & 21.

[74]FINEBERG REPORT *supra* note 12, at 36.

[75]*Cf.* Havighurst, *More on Regulation: A Reply to Stephen Weiner*, 4 AM. J.L. & MED. 243, 247-49 (1980) (disputing claims by a Massachusetts advocate of regulation that politicized regulation is legitimized by the democratic process and should be immune to general criticism).

which should not be limited to assessing the technology's status as "experimental" or otherwise.[76] The Report also makes clear that in the task force's view, availability is synonymous with general reimburseability.[77] It opines, too, that general availability should not result only through the state Medicaid program's becoming "the de facto insurer for all such procedures,"[78] by virtue of inadequate private financing and the impoverishment of transplant candidates. To prevent this result and to "ensure fairness in the distribution of burdens regarding reimbursement," the Report suggests that coverage be prescribed by a "joint committee" of government representatives and private insurers.[79] Such a body might violate the federal antitrust laws, however, unless its decisions were embodied in official government action.[80]

Recommendations (3) and (4) by the OTTF introduce the issue of costs. During the evaluation period, authority to do transplants would be granted only to those hospitals that agree to perform them within the MAC, with an exception for each procedure that amounts to the costs of organ procurement and cyclosporin.[81] This attempt to force hospitals to finance a portion of the cost of transplant programs by economizing was apparently the only way, even in this heavily regulated state, in which the volume and hence the overall cost of transplants could be kept down. To protect against the concomitant risk that transplantation would displace other vital services, recommendation (3) suggests that need determinations in the DON program be made only upon a showing that the cost of adding transplantation can be borne without sacrificing more desirable services. "As a principle, the Task Force believes that if it turns out that liver and heart transplantations take resources away from higher priority health care services, and decrease their accessibility to the public, then transplantation procedures should not be performed."[82]

In a section antecedent to its specific recommendations, the OTTF gives its final word on how to prevent a modest amount of costly transplantation from diverting resources from essential services:

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[76]OTTF REPORT, *supra* note 67, at 11.

[77]*Id.* at 11-12.

[78]*Id.*

[79]*Id.*

[80]In general, the Sherman Act, 15 U.S.C. § 1 (1983), prohibits collective actions of the kind that are taken for granted in centrally governed health care systems as a useful adjunct or alternative to direct government control. Although the McCarran-Ferguson Act, 15 U.S.C. § 1001 (1983), provides a partial exemption from the Sherman Act for "the business of insurance," an agreement not to sell a certain type of coverage has been held to fall within an exception to this exemption. St. Paul Fire & Marine Ins. Co. v. Barry, 438 U.S. 531 (1978).

[81]OTTF REPORT, *supra* note 67, at 14. Such costs would amount to about $9000 per heart transplant and $44,000 per liver. *Id.*

[82]*Id.* at 13.

> [T]he Task Force believes that these procedures should be performed on [all] those who are likely to benefit from them, so long as the total cost is controlled, and resources are not diverted from higher priority medical procedures to liver and heart transplantation. The question of what a "higher priority" procedure is will be based on the total number of individuals affected, and the importance to their lives of the intervention. For example, it *may* be appropriate to shut down an underutilized maternity program to do organ transplants. The burden of demonstrating that such a tradeoff is appropriate, however, should be on the hospital proposing it. Accordingly, in the [DON] process, all currently available health care services should be presumed to be higher priority than transplantation. The applicant should have the burden of demonstrating that transplantation has a higher priority than any other currently available health care service from which organ transplantation diverts funds and/or support systems.[83]

Such an allocation of the burden of proof would apparently require a hospital to prove its own past inefficiency and waste of public resources in order to qualify for the establishment of a transplant program; a well-run hospital doing only things highly beneficial to patients need not apply. Such paradoxes are common under regulation. Perhaps the crowning irony, which the task force itself notes in its chapter on costs,[84] is that transplantation can be contemplated in Massachusetts only because much of its high cost can be paid out of waste in the system—the very thing that regulation was supposed to prevent. The presumption that the OTTF created against the displacement of existing services by transplants can hardly be taken, in context, as an expression of faith that regulation has in fact achieved true efficiency.

Recommendation (5) addresses patient selection criteria and would require them to be "public, fair, and equitable" and based initially on medical suitability criteria and secondarily on the principle of first-come, first-served, in the event demand exceeds the supply of organs.[85] For Massachusetts residents, the ability to pay should not be a factor, nor should social class or family support.[86] The report suggests an "appeal mechanism" to ensure fairness, thereby conjuring up a vision of two lawyers advocating their dying clients' competing claims to a single liver before a neutral decisionmaker. This is a particularly striking example of how far the OTTF would go to ensure that the state appear legalistically fair

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[83] *Id.* at 9, 10.
[84] *Id.* at 60.
[85] *Id.* at 16-17.
[86] *Id.*

in dispensing life and death.[87] With almost equal plausibility, the report could have required that patient selection reflect "affirmative action" aimed at redressing past societal injustices toward certain groups.

Finally, recommendation (6) introduces the idea that heart and liver transplants in the Commonwealth should be undertaken by hospitals belonging to a consortium organized to share data, experience, and resources.[88] This idea apparently did not originate with the OTTF because it stated that there is no economic justification for beginning organ transplantation at more than one hospital, but that if more than one hospital is to do the procedure, there must be a truly integrated and cooperative effort—a "worthwhile consortium."[89] The consortium concept had appeared earlier in a staff recommendation by the Department of Public Health in connection with the pending DON application.[90] In addition, the consortium idea was dictated in part by the state's refusal to grant a MAC exception, thereby drastically limiting the number of procedures that any one institution could afford to perform.

Use of several institutions put the regulators on very shaky ground, however, in light of another prime goal of regulation—ensuring the quality of care. Because it is widely accepted that experience improves outcomes, the Department of Public Health could have been criticized if it authorized several hospitals each to perform less than the optimal number of procedures per year. The consortium concept, if it allows experience truly to be shared, overcomes this objection.[91] Its adoption in Massachusetts, however, appears to have been only a face-saving compromise, necessitated by the political unpopularity of giving all the business to one institution.[92]

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[87]For warnings of the consequences of excessive "due process" in dealing with sensitive issues of this kind, see Blumstein, *Constitutional Perspectives on Governmental Decisions Affecting Human Life and Health*, LAW & CONTEMP. PROBS., Autumn 1976, at 231; Havighurst, Blumstein & Bovbjerg, *supra* note 4, at 155-57. For scholarship approving the legalistic approach, see J. KATZ & A. CAPRON, CATASTROPHIC DISEASES: WHO DECIDES WHAT? 239-40, 246-48 (1975); Note, *Due Process in the Allocation of Scarce Life Saving Medical Resources*, 84 YALE L.J. 1734 (1975).

[88]OTTF REPORT, *supra* note 67, at 18-20.

[89]*Id.*

[90]*Id.* at app. B.

[91]A factitious consortium, however, could result in significantly poorer patient outcomes. This reasoning was the substance of an ultimately unsuccessful challenge mounted by the OTTF's chairman to the later-proposed Boston heart consortium. *See* Brief for Appellant at 10-13, George J. Annas Ten Taxpayer Group v. Department of Public Health (Health Facilities Appeals Board argued July 9, 1985) (Project No. 4-3306).

[92]George Annas has described the consortium concept as "primarily a political issue . . . grafted onto the original draft of the Report at the request of the Commissioner of Public Health." Annas, *Regulating Heart and Liver Transplants in Massachusetts: An Overview of the Report of the Task Force on Organ Transplantation*, 13 LAW, MED. & HEALTH CARE 4, 5 (1985).

The consortium approach solved problems for a number of the participants in the drama. The consortium idea was initially attractive to the Department of Public Health because it would relieve it of the politically difficult task of choosing among powerful institutions. MBCBS, which took credit for planting the seed of the consortium concept, were probably hoping to avoid having to select among or oversee competing hospitals or to adopt their own patient selection criteria.[93] The four hospitals seeking authority for liver transplants had figured out for themselves the advantages of a united front both in seeking a DON[94] and in avoiding possible future competition.

B. The Egalitarian Motif

Perhaps the most notable feature of the OTTF report is its strong emphasis on equality in the distribution of transplanted organs. Perceiving this as the central question in the morality play, the task force declaimed:

> On the issues of equity and fairness, we concur with the conclusions of the President's Commission for the Study of Ethical Problems in Medicine: society has an ethical obligation to ensure equitable access to health care for all; and the cost of achieving equitable access to health care ought to be shared fairly. *Transplantation of livers and hearts should therefore only be permitted if access to this technology can be made independent of the individual's ability to pay for it*, and if transplantation itself does not adversely affect the provision of other higher priority health care services to the public.[95]

A literal reading of the italicized lines indicates that the OTTF not only endorsed the provision of transplants to those who cannot afford them, but also took the startling position that paying patients should be denied transplants in Massachusetts until such time as every equally needful patient could get one. As noted earlier, it is easily within the power of Massachusetts regulators—without actually making the performance of this therapeutic procedure a criminal act[96]—to prevent a dying patient from purchasing a transplant with his own money from will-

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[93]Young interview, *supra* note 47.

[94]Some members of the OTTF viewed the consortium concept with suspicion, considering it an end run around the DON process that permits four programs rather than just one to perform transplants and makes it easier for the hospitals to demonstrate that other services are not being displaced. *Cf.* Brief for Appellant, *supra* note 91, at 9-10 (makes this argument with regard to the proposed heart transplantation consortium).

[95]OTTF Report, *supra* note 67, at 9-10 (emphasis added).

[96]Outright state prohibitions of therapeutic procedures can raise a constitutional issue. *E.g.*, Roe v. Wade, 410 U.S. 113 (1973) (abortion); Rogers v. State Board of Medical Examiners, 371 So. 2d 1037 (Fla. Dist. Ct. App. 1979) (chelation therapy). Regulatory programs having comparable effects are more difficult to challenge legally but should raise similar concerns.

ing providers. The OTTF apparently approved the use of the state's prohibitory powers in this way in order to coerce a public desirous of transplants for themselves into providing them for everyone. Probably, however, the task force never expected that such extortionate use of the state's regulatory power would actually be necessary to effectuate its policy objective of equity in transplantation.[97]

Although the OTTF may not have meant what it said about withholding transplants from paying patients as an inducement to the procedure's equitable provision, the OTTF was clearly unresponsive to the interests of those citizens who would not require the state's assistance to finance a transplant. Under the report's recommendations, transplants will occur only on the state's own terms, and only a limited number of transplants will be performed, regardless of the availability of organs. Because recipients of these few procedures must be selected, some patients who could and would pay their own way will not get treated.[98] Yet, if they were allowed to purchase their own treatment outside the MAC system, there would be no diversion of resources from "higher priority" health care. The OTTF appears content with a state policy that could deny a transplant to a dying person who had made explicit financial provision for it. The best explanation for this complacency in the face of a denial of lifesaving medical care may be simply that the OTTF members had lost the capacity to conceive of the purchase of health services as a private matter. If so, their attitude reveals a great deal about the political culture of Massachusetts and its approach to health care.

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[97]The DON for the liver transplantation consortium had already been granted in January, and a heart transplantation DON was issued in May. Letter from Department of Public Health to Dr. Richard Nesson, Brigham and Women's Hospital, May 16, 1984, *reprinted in* OTTF REPORT, *supra* note 67, at 129.

[98]The OTTF may have viewed this as only a theoretical danger. It may have expected, for example, that all medically defensible transplants would in fact be provided. Disagreement is likely, however, over whether a particular procedure is desirable or "indicated," and it is well-documented that as a technology improves, the medical indications for its use broaden. *See* Caplan, *Organ Transplants: The Costs of Success*, HASTINGS CENTER REP., Dec. 1983, at 23, 31. The OTTF also might have thought that anyone who could afford the procedure could also afford to travel out of state to get it. This proposition holds true, however, only if other states reject a Massachusetts-type hostility to transplantation and also permit outsiders to obtain organs and if the patient's ability to pay does not stem from the purchase of health insurance, which typically does not cover the many additional expenses associated with out-of-state treatments. Although the OTTF may have had reason to discount the risk that some self-supporting patients would be denied desired transplants, its report expressly recognizes that the number of people waiting for transplants might exceed the number of procedures that could be done. It is possible that it is simply not fashionable in Massachusetts publicly to express concern about the "right to health care" of anyone except the poor.

C. Denouement

The OTTF Report was received by the Public Health Council of the Department of Public Health and was the subject of a public hearing on November 5, 1984. The council unanimously adopted the report's recommendations as official policy and instructed the Department to use the text of the report for guidance in DON proceedings. The current state of organ transplantation in Massachusetts appears to have followed the outlines of the OTTF's script. There are questions, however, whether the spirit of its recommendations has been observed in practice. For example, it is doubtful that hospitals seeking DONs for transplantation have given any real guarantee that "higher priority" services will not be affected. Also, it has been questioned whether the consortium is really functioning as an integrated research program dedicated to collecting useful data for later evaluation by a "publicly-accountable body."[99] It would appear that the drama is not yet over.[100]

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[99]*See infra* note 117. Both the OTTF and the Department of Public Health contemplated a later evaluation of the liver transplantation program to see whether higher priority services were being displaced and expected that the data collected would shed light on this issue, on which the consortium would have the burden of proof. The first annual report of the consortium, covering January 26, 1984, to January 26, 1985, was brief, even cursory, and seems not to contain the data required by the DON, let alone data that could prove anything about displacement. BOSTON CENTER FOR LIVER TRANSPLANTATION, 1984 ANNUAL REPORT (1985). Even the actual costs of transplantation per survival year are impossible to calculate from the report. Patients' rehabilitation status is only sketchily assessed, and no data are supplied as to the basis for rejection of candidates or the current health status of those rejected. *Id.* Without comparative outcomes, it is impossible to judge the procedure's value or the predictive effectiveness of the patient selection criteria used. There is also no evidence that transplants have not displaced desirable services.

Some OTTF members, including Chairman George Annas, argue that the coalition is violating at least the spirit of its DON. Annas interview, *supra* note 71. The Department of Public Health seems to feel, however, that because the data collection requirements for livers were never very well defined, the coalition's first report is satisfactory. Gorga interview, *supra* note 44. At a recent conference, panelists discussing the Massachusetts system—including Public Health Commissioner Walker, transplant surgeon Roger Jenkins, OTTF chairman Annas, and economist Marc Roberts—disagreed in almost every particular regarding whether the Department and the consortium were doing what they were expected to do. CONFERENCE ON TRANSPLANTATION AND ARTIFICIAL ORGANS: ISSUES ALONG THE EXPERIMENT-TO-THERAPY SPECTRUM (Nov. 1985). The lack of agreement on a variety of issues suggests that the apparent consensus surrounding the OTTF Report resulted from a failure to address practical issues and a papering over of potential problems. Indeed, at the conference just cited, OTTF chairman Annas labeled the OTTF "a quasi-Quixotic noble failure." *Id.*

[100]At present, however, the even more complicated debate over heart transplantation in Massachusetts is apparently diverting much attention from the liver issue. Gorga interview, *supra* note 44; *see supra* note 91. The parties to this debate are more experienced and sophisticated than they were at the time of the liver debate. In particular, Massachusetts expects to employ many of the recommendations developed by the Battelle Human Affairs

III. Reviewing the Performance

Viewers of the morality play "Liver Transplantation in Massachusetts" must come away unsatisfied but instructed in the difficulties of putting life-and-death choices on the political stage. Perhaps more than any other state, Massachusetts, aided and abetted by a powerful intellectual community, has assumed the role of dominant decisionmaker in health care matters. The case of liver transplantation provides a unique test of the ability of at least one model of a monolithic, highly regulated, and politicized health care system to address difficult choices involving expensive medical technology.[101]

In the Massachusetts system, it was necessary for the state to decide publicly whether to allow liver transplantation at all, and the action of the drama was ostensibly about the making of this choice. Politically, however, the state probably never really had the option of rejecting transplants once major research institutions resolved to perform them and the media concluded that access to them was the right of every Commonwealth citizen. As in a Greek tragedy, the outcome was foreordained, and the characters were never truly free to alter the inevitable result. It is in the nature of "tragic choices" that once they become political, they are driven mainly by forces beyond the power of individuals to control or escape.[102] To accept the decisions emerging from the black box of Massachusetts state government as appropriate societal choices is to ignore not only the previously-noted questionable features of the political process, but also the shortcomings of regulation, some troublesome ethical issues, and the possible availability of alternative decisionmaking mechanisms.

A. Regulatory Inadequacies

Having approved transplants in principle, the Commonwealth of Massachusetts and its respective task forces then had the problem of

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Research Center. *See* R. Evans, National Heart Transplantation Study; Final Report (1984) (prepared by the Battelle Human Affairs Research Center for Health Care Financing Administration, DHHS, Washington, D.C.)

[101]*See supra* note 8. A particularly interesting point of comparison is provided by the Minnesota Coalition Report which, as the product of a private organization, is much less a political document than the OTTF report. Minnesota Coalition Report, *supra* note 8.

[102]Keeping such issues out of the political arena is itself difficult. As a societal attempt to resolve the tragic choice by finessing it, this strategy, like others, is apt to be unstable precisely because it sacrifices important values, such as openness and explicitness. Professor Calabresi predicts an inevitable and continuing oscillation among imperfect solutions as society continually reasserts those values (equity, efficiency, freedom, etc.) that are being neglected by whatever system of choosing is currently in place. *See* G. Calabresi & P. Bobbitt, *supra* note 5, at 195-99. However, whether a stable system can be designed or happened upon without explicit policy choice is an empirical question. In any case, depoliticization would appear to be a vital first step toward possible stability.

rationing the costly procedure. However, the Massachusetts regulatory scheme, despite its comprehensiveness and complexity, provided no public mechanism for deciding explicitly how often and under what circumstances the procedure would be done. As one protection against high costs, the task forces recommended against a complete pass-through of expenditures for transplants, thus forcing hospitals to look elsewhere for at least some of the necessary funds. Under the state's regulatory control of hospital revenues, virtually the only way for a hospital to generate such funds would be to cut back its other activities. The OTTF's response to the danger that transplants would displace more valuable hospital services was to instruct the DON agency to withhold approval of a transplantation program that could not prove that only relatively wasteful activities would be eliminated in order to accommodate it. As a regulatory standard, this requirement was highly impractical and unrealistic,[103] but it protected the task force against the criticism that it had authorized a diversion of resources to lower-priority uses.

With all their regulatory paraphernalia, Massachusetts officials lack the statutory powers they need to control directly the volume and cost of transplants. As to these and all other medical procedures, the state can only identify institutional providers of needed services and control, in a rough way, the total resources at each institution's disposal. Because these powers do not add up to effective control of medical technology, the level of transplantation activity in Massachusetts remains ultimately in the hands of prestigious doctors and hospitals, subject to certain resource constraints. Although limiting the resources available to providers can control aggregate costs, the Massachusetts MAC controls relate in no recognizable or rational way to the potential benefits or costs of any particular procedure. Allocational decisions are thus left in providers' hands.[104] Once Massachusetts is satisfied that the resources used in organ transplantation are not obtained by eliminating "higher priority" health services currently being provided, it permits transplants to proceed without regard to the additional possibility that those resources might have still other, more valuable uses.

Thus, although Massachusetts has made it appear that it has exercised statesmanlike control in this highly publicized area, it may have done nothing more than give certain Boston hospitals the green light to rearrange institutional priorities to facilitate new adventures on the frontiers of medicine. The main constraint on these institutions is the risk

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[103]See *supra* note 99. Two critics of the OTTF's burden-of-proof recommendation for DON proceedings have said, "[I]t is difficult to imagine a process that is more conceptually confining, less amenable to empirical analysis, and more open to subjective interpretation." Overcast & Evans, *Technology Assessment, Public Policy and Transplantation: A Restrained Appraisal of the Massachusetts Task Force Approach*, 12 LAW, MED. & HEALTH CARE 106 (1985).

[104]*See supra* note 36.

that their actions will offend future state officials or the "publicly-accountable body" that the OTTF recommended to evaluate transplantation later on. The implicit threat that the state might take unspecified action in the future puts the participating institutions on notice that they had better be able to defend their use of resources or face unpleasant consequences. Such is life in a centrally managed health care system, where things fortuitously attracting public notice receive minute attention while well enough is left alone. Politicization of transplantation achieves control for its own sake but provides little assurance that resources will be put to their best use. A regulatory system that purported to make all the necessary allocational choices would be a more stifling form of regulation than even Massachusetts would be likely to tolerate.

B. Questions of Values

Above all, Massachusetts strove for ethical high ground in establishing its position on liver and heart transplants. Yet a careful reading of state policy as reflected in the OTTF report reveals a willingness to countenance the denial of transplants to paying patients—not out of any paternalistic concern, but simply because some other person in comparable condition could not afford the same treatment. Perhaps it was the prospect of organ shortages and bidding wars that only the well-to-do could hope to win that induced the OTTF to approve the denial of transplants to paying patients. After all, the question of how to ration scarce medical resources has long inspired ethicists to philosophical debate,[105] and the OTTF, chaired by a leading participant in that debate,[106] may have assumed that it had been convened primarily for the purpose of prescribing an ethically satisfying system for rationing scarce organs.[107] The

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[105]The relevant literature is voluminous. For general sources, each of which itself draws on many others, see N. DANIELS, JUST HEALTH CARE (1985); IN SEARCH OF EQUITY: HEALTH NEEDS AND THE HEALTH CARE SYSTEM (R. Bayer, A. Caplan & N. Daniels eds. 1983); H. SMITH & L. CHURCHILL, PROFESSIONAL ETHICS AND PRIMARY CARE MEDICINE (1986); Childress, *Rationing of Medical Treatment*, in 4 ENCYC. OF BIOETHICS 1414 (W. Reich ed. 1978).

[106]*See, e.g.*, Annas, *No Cheers for Temporary Artificial Hearts*, 15 HASTINGS CENTER REP. 27 (Oct. 1985); *The Phoenix Heart: What We Have To Lose*, 15 HASTINGS CENTER REP. 15 (June 1985); *Allocation of Artificial Hearts in the Year 2002: Minerva v. National Health Agency*, 3 AM. J. LAW & MED. 59 (1979).

[107]The OTTF's apparent eagerness to respond to that charge may be seen in its failure to consider seriously the possibility of encouraging the sale of organs by families of deceased potential donors to those awaiting transplants. OTTF REPORT, *supra* note 67, at 37. A market for organs would eliminate shortages and the need for rationing systems to allocate a limited supply. However, instead of seeking to break down the current cultural taboo against the buying and selling of body parts, *see* the National Organ Transplantation Act, *supra* note 71 (prohibiting the sale of organs in interstate commerce), the OTTF took the easier political path. Indeed, it may have welcomed organ shortages

OTTF did not, however, expressly restrict its recommendations to situations where there were not enough organs to go around. As it appears, the OTTF was entirely comfortable with a policy that would force self-supporting transplant candidates to join (and perhaps die in) the state-mandated queue even if an adequate number of organs was available.

In support of its willingness to deny transplants to paying patients, the OTTF invoked a well-known 1983 report by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[108] Although the President's Commission did declare that society has an ethical obligation to guarantee a decent level of health care to its neediest citizens,[109] nowhere did it indicate that it would be ethical to hold the wealthy and well-insured sick hostage without treatment until society honored this obligation. Moreover, the President's Commission clearly stated that it was not ethically necessary for all citizens to receive the same health care.[110] Thus, it certainly laid no foundation for the Massachusetts policy of forcing all transplant candidates to take their chances in a state-sponsored life-and-death lottery.

The OTTF again misrepresented the President's Commission in citing its report as authority for guaranteeing procedures as costly as liver and heart transplants to persons who cannot afford the insurance necessary to purchase them.[111] Although recognizing a public obligation to provide a decent minimum level of health services to all, the Commission did not fully define that level or specify what services should be included in the guaranteed package. Moreover, there are numerous reasons why one might conclude that procedures as costly as liver transplants ought not to fall under society's guarantee until the nation becomes a great deal wealthier and has met a great number of other needs, including non-health needs, of its less advantaged citizens.[112] The OTTF seemed

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as a constraint on the number of costly procedures and as an excuse for implementing their rationing theories. *See, e.g.*, OTTF REPORT, *supra* note 67, at 80, 83.

The shortage of organs is currently being addressed by donor education efforts, ranging from promoting the slogan "Organ Donors Recycle Themselves" to legislation requiring hospitals to request donations from families of potential donors.

[108]*See supra* text accompanying note 95 (citing PRESIDENT'S COMMISSION REPORT, *supra* note 41).

[109]The President's Commission Report states as its first premise that "society has an ethical obligation to ensure equitable access to health care for all," and continues: "Equitable access to health care requires that all citizens be able to secure an *adequate* level of care without excessive burdens." PRESIDENT'S COMMISSION REPORT, *supra* note 41, at 4 (emphasis added).

[110]*Id.*

[111]OTTF REPORT, *supra* note 67, at 74.

[112]As the President's Commission explains:

> [T]he standard of adequacy for a condition must reflect the fact that resources used for it will not be available to respond to other conditions. Consequently, the level of care should reflect a reasoned judgment not only about the impact

to conclude that the mere fact that transplants may save lives is enough to obligate society to pay[113]—despite the explicit finding that at $230,000 to $340,000 per patient surviving one year, liver transplants were several times more costly than the most costly of other generally accepted medical treatments.[114] The OTTF thus backed itself into an ethically debatable position. While arbitrarily treating transplantation as being so valuable that it should be available to all, it also declared that because of the expense, only those transplants that could be financed primarily out of system waste should be provided. Thus, the OTTF's desire to demonstrate its and Massachusetts' commitment to providing lifesaving treatment for all led it to restrict transplants' availability to all patients, including those who would not require public financing. Such a policy had specifically been denounced by the President's Commission as "an unacceptable restriction on individual liberty."[115]

Under the circumstances, it seems probable that the OTTF and the Commonwealth were more concerned with performing a symbolic act than with giving the poor the essentials of a good life. Indeed, although the OTTF explicitly endorsed the equitable distribution of transplantation as an available means of "prevent[ing] the gulf between the haves and have nots from widening,"[116] the primary beneficiaries of the transplant

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> of the condition on the welfare and opportunity of the individual but also about the efficacy and the cost of the care itself in relation to other conditions and the efficacy and cost of the care that is available for them.

PRESIDENT'S COMMISSION REPORT, *supra* note 41, at 36; *see supra* notes 41 & 70.

[113]The OTTF's conclusion that organ transplantation should be part of that adequate level of care is apparently justified by the stated public perception that transplantation is "life-saving." OTTF REPORT, *supra* note 67, at 5. The President's Commission Report, however, does not contemplate and indeed does not seem geared toward addressing the inclusion of extreme and expensive technologies in the guaranteed minimum level of care. For example, it states:

> Society will reasonably devote some resources to health care but reserve most resources for other goals. This, in turn, will mean that some health services (even of a lifesaving sort) will not be developed or employed because they would produce too few benefits in relation to their costs and to the other ways the resources for them might be used.

PRESIDENT'S COMMISSION REPORT, *supra* note 41, at 19.

[114]On cost figures, see OTTF REPORT, *supra* note 67, at 43-69. These figures have been criticized as excessive. *E.g.*, Overcast & Evans, *supra* note 102, at 107. *See supra* text accompanying notes 17 & 20.

[115]PRESIDENT'S COMMISSION REPORT, *supra* note 41, at 20; *see also id.* at 4, 18; Pauly, *Equity and Costs*, 13 LAW, MED. & HEALTH CARE 28 (1985). A better reading of the President's Commission Report surely would conclude that the state ought to ensure equitable access to lower-cost, higher-priority services, leaving expensive technologies outside the "decent minimum" but available for purchase by those who choose to devote personal resources to that end.

[116]OTTF REPORT, *supra* note 67, at 75; *see* Pauly, *supra* note 115, at 29. The OTTF surely places disproportionate emphasis on catastrophic health care as a way to rectify perceived injustices in the social order. It is open to challenge not only by those who

policies adopted were not the less well-off populations, from which a few transplant candidates might come, but those who could take public credit for making the humanitarian choice. The OTTF members, the public officials involved, and the citizens of Massachusetts as a whole avoided appearing cold-hearted and uncaring in the face of imminent death by symbolically extending lifesaving assistance to a handful of afflicted patients. The troubling question remains, however, whether the Commonwealth has so far discharged its other, perhaps greater responsibilities to its disadvantaged citizens that those basking in the glow of this good work are truly entitled to feel good about themselves.

C. The Alternative of Off-Stage Choices

Whenever tragic choices are made upon a public stage, it is probably inevitable that the actors will play to the audience, sacrificing some values, particularly allocative efficiency, in order to be seen as acting vigorously in the defense of human life. Before one can criticize the performance in Massachusetts, therefore, it is necessary to ask whether there is any way in which these difficult issues could have been resolved without public posturing and with a greater expectation that resources would not be used in pursuit of health benefits too modest to justify the outlays. Can the role of politics in these difficult matters be limited? One discussion of this question frames the challenge as follows:

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would be prevented from purchasing transplants but also by the have-nots in question, who might reasonably choose to have the resources applied where they have greater need and can expect greater benefit. It appears, however, that the OTTF had a larger political agenda. Chairman Annas has acknowledged as much in responding to criticisms such as those suggested here:

> The Task Force . . . saw its charge as an opportunity to express our views on how the system *ought* to work. The Task Force believed that fairness and equity are critical values that are more important than perpetuating a system where only the rich and those with the right insurance or publicity acumen can obtain transplants. The fact that we have not tried for equity and fairness elsewhere in the system does not make it somehow wrong to take the opportunity we have in heart and liver transplantation to try to introduce equity and fairness in the real world. We must begin somewhere. Anywhere will entail some arbitrariness. But the symbolic nature of transplantation, and its ability to capture the public's attention and support, commend it as a reasonable place to begin. Far from presuming "the validity of the status quo," the Task Force believed that transplantation provides a unique opportunity to modify some of the the health care system's fundamental operating assumptions.

Annas, *The Dog and His Shadow: A Reply to Overcast and Evans*, 13 LAW, MED. & HEALTH CARE 112, 113 (1985). Annas's visionary goal is, however, as remote as ever. The OTTF Report's passionate concern for equity ironically succeeds only in raising to the level of principle the political preference for identified over statistical lives, while doing little to clarify the debate over the extent to which government should guarantee the provision of health care services.

> [A]lthough there are good reasons for our society to seek to spare its individual members catastrophic health care costs, in doing so it will almost inevitably commit more resources than it really wants to commit, or should commit, to such a purpose. This result is probable because government will find it difficult to impose, or even tolerate, needed limits on very expensive medical efforts to save lives and preserve health without seeming to deny the sanctity of human life. The challenge is thus to design social institutions which neither unduly sacrifice society's humanitarian ideals nor overspend on medical services not warranted by the benefits they yield. . . . [G]overnment cannot safely assume too central a role in decisionmaking on life-and-death and similar issues and . . . society will be better off if institutional arrangements are such that death and suffering from catastrophic disease continue to be perceived as "more an act of God than of the legislature." Careful attention to program details and to the allocation of decisionmaking responsibility is necessary if society is to succeed, in the context of expanded protection against catastrophic medical expenses, in preserving both humanitarian values and democratic government's benign —if not its beneficent—image.[117]

The quoted study "identifies a critical need to keep government's profile low in order to facilitate saying 'no' when it is appropriate to do so" and "seeks to help government limit its moral as well as its financial exposure while honoring a substantial commitment to assist victims of catastrophic disease."[118]

The Massachusetts performance reviewed here casts only a little light on the possibility that government can be removed from center stage in these dramas and that there can be introduced instead the *deus ex machina* of an unregulated, demand-driven market for health services. The foundation of the Massachusetts system is, after all, the assumption that regulation is essential to prevent inefficient growth and wasteful spending on health services of all kinds. Although there was a time when this assumption seemed unchallengeable, actual reforms in some health care financing mechanisms have recently begun to reveal the potential of private purchasing decisions in a competitive marketplace to curb the excessive flow of resources into the health care sector and to confine spending to activities that are relatively cost-effective.[119]

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[117]Havighurst, Blumstein & Bovbjerg, *supra* note 4, at 123-24 (quoting ARTIFICIAL HEART ASSESSMENT PANEL, NAT'L HEART & LUNG INST., THE TOTALLY IMPLANTABLE ARTIFICIAL HEART 247 (1973) (separate views of C. Havighurst)).

[118]*Id.* at 124.

[119]*See, e.g.*, Arnett, *Health Spending Trends in the 1980's: Adjusting to Financial Incentives*, HEALTH CARE FIN. REV., Spring 1985, at 1; Davis, *Is Cost Containment Working?*, HEALTH AFF., Fall 1985, at 81.

Certainly what is known about the efficacy and costs of liver transplantation does not suggest that only irrational or impoverished persons would ever choose to forgo this treatment even in the face of certain death.[120] It thus may be socially desirable and practically feasible to leave decisions about whether or to what extent to cover liver transplantation to private choices of employers, health insurers, and organized health plans, all of which are accountable to consumers in a competitive market.[121] Even where public financing is necessary, government may recede from its current role as dominant decisionmaker by cashing out current in-kind benefits and letting beneficiaries shop for private coverage with financial help in the form of a government-supplied voucher.[122] In this fashion, government can fulfill its responsibility for providing a decent minimum level of health services without having to rule definitively on what services beneficiaries must select.

Whether the performance of a competitive, demand-sensitive market for health care will satisfy the full range of public expectations is still an open question, but there is at least some evidence that health care consumers and providers are now economizing in ways previously resisted. Thus, it may be possible

> to eschew trying to solve the [catastrophic disease] problem in any definitive fashion and instead to take steps to enhance each

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[120]Available data suggest not only that liver transplantation is uniquely expensive but that it can plausibly be viewed as of questionable benefit. Although the OTTF Report's survey of liver transplantation morbidity and mortality is brief, OTTF Report, *supra* note 67, at 29-32, other sources raise some important questions concerning the toxicity of cyclosporin, the effect of long-term administration of immunosuppressive drugs on the growth and development of children, and the near-total lack of measures of the quality of survivors' lives. *See* Nat'l Center for Health Services Research, DHHS, Liver Transplantation (1983); Starzl, 1 Transplantation Proceedings (1985). The OTTF addressed these major concerns only in connection with the prospect that too many transplant seekers might die in the state-mandated queue; if this happens, the OTTF Report advocates that individuals meeting the medical criteria for inclusion "be persuaded not to attempt to join the queue" by telling them the truth about transplantation. OTTF Report, *supra* note 67, at 83. The implication is that if people understood all of the risks, consequences, and side effects of transplantation and their implications for the duration and quality of life of survivors, a significant number of candidates would voluntarily forgo the procedure. One would suppose that potential candidates deserve the opportunity to achieve that full understanding regardless of the size of the organ supply. The OTTF was even farther, of course, from seeing any connection between doubts about the value of the procedure and the procedure's extraordinary costs; it was also opposed to letting individuals compare likely benefits and costs before deciding whether to invest in the necessary insurance. *Id.* The Minnesota Coalition Report specifically contemplates such choices. Minnesota Coalition Report, *supra* note 8, at 47-48.

[121]Allowing individual consumers to exercise free choice creates problems of adverse selection and may be questionable policy for other reasons. *See infra* note 124.

[122]*See* Minnesota Coalition Report, *supra* note 8, at 38-41. This report discusses two alternative strategies for "implementing the 'basic level of health care' principle." *Id.* One of these is a voucher-type strategy that would leave the private sector substantial decisionmaking freedom.

> individual's ability to solve his own personal problem by choosing among a variety of available options, with public financial assistance where necessary. Such a strategy lacks the tidiness and specificity which policymakers often desire and would doubtless leave many residual problems. . . . But the fundamental values of pluralism and freedom . . . suggest an obligation not only to tolerate but also to foster diversity on matters as intensely personal and private as the means of coping with life-threatening disease and the attendant tragic choices.[123]

Such an approach provides a major challenge to society's ability to educate consumers and foster rational decisionmaking about low-probability events.[124]

The Massachusetts experience with liver transplantation yielded one interesting datum helpful in appraising the market alternative when MBCBS offered TIP at an actuarially fair price to their group accounts and fewer than one third of them accepted the offer. Unanswered, of course, are many questions, including the ultimate one—whether a situation in which some citizens are protected against a highly visible health care need and others are not is a stable and tenable one or one that would disintegrate upon the appearance of a transplant candidate who

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[123]*See* Havighurst, Blumstein, & Bovbjerg, *supra* note 5, at 189.

[124]The simple view is that "organ transplantation is the epitome of an insurable event; transplants are random, rare, their risk probabilities are measurable, and transplants are prohibitively expensive for most individuals." MINNESOTA COALITION REPORT, *supra* note 8, at vi. But letting *individuals* choose is not necessarily the optimal policy. For example, Calabresi observes:

> I'd like to know, for instance, if any individual does value his own life in a way that can meaningfully be used in choosing between life and death risks. If each of us were paid to take a one in a million chance to lose our life, realistically, how much would we ask? How much more would we ask if the chance of death were one in one thousand? Or one in two? I would suggest that the value that most of us would give to our lives would not be the same value in the three cases, after discounting by mathematical risk. In other words, the value we as individuals put on our life is not independent of the gamble we are taking. This fact makes it very, very difficult as a practical matter to define any value as the appropriate one in creating incentives for safety.

Calabresi, *Commentary*, in ETHICS IN HEALTH CARE 48, 52 (1974). For findings from psychological research suggesting inconsistencies and incoherence in consumer decisions that require the weighing of risks and valuation of alternative outcomes, see Kahneman & Tversky, *The Psychology of Preferences*, 246 SCI. AM. 12 (1982); Tversky & Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 SCI. 453 (1981). Although these difficulties suggest the shortcomings of individual choice, most market choices of insurance coverage are not made by uninstructed consumers. Instead, they are most likely to emerge from collective processes in employment groups and to reflect the sophistication of employers, insurers, and medical care providers. Such collective choices are likely alone to reflect both shared values and the existence of alternative uses of the resources at stake.

turned down the available protection. This empirical question deserves more thoughtful attention than it has yet received. For example, it would not be conclusive evidence against relying upon market choices to ration transplantation if an occasional patient should receive, at an employer's or insurer's expense, a treatment that was not included in purchased coverage. Informal provision of such charity for occasional exceptionally appealing cases is not an unthinkable alternative to the Massachusetts rationing system. Indeed, it could supply just the buffer against highly publicized denials of care that is needed to maintain an effective barrier to spending vast resources on marginally beneficial treatments.

Attention must also be given to the design of coverage that can survive the inevitable questioning and legal challenges. One can imagine, for example, insurance policies that provide liver transplants for the most appealing patients, such as children, but deny them to victims of less attractive diseases, such as alcoholism. Other mechanisms for controlling costs and ensuring quality include limiting coverage to transplants obtained in centers that have been identified by the insurer as efficient and low-cost. Although much remains to be learned about whether and how to purchase this costly and still questionable service, privatization of catastrophic insurance, perhaps with tax and other incentives to encourage coverage broad enough to minimize the demoralizing effects of tragic choices, would seem to make possible sensible rationing techniques that the public sector could not itself sustain.[125]

Perhaps the best way to conclude this reflection on how society handles these difficult matters is to ask how these problems will be addressed a hundred years from now. Is there any doubt that society will somehow reassess its commitment to saving lives without regard to cost and will come to accept as a matter of course some deaths that could be prevented by the application of high technology? There are many different ways in which patients can be selected for treatment, not all of which require reliance on government to act directly or indirectly as the giver or denier of life itself. Without question, our attitudes toward such matters are changing. Ultimately we must give up some cherished but so far unexamined collective beliefs. The frightening but certain truth is that we are acting out our own morality play—one in which some simplistic values, of the kind that flourish most in a political environment, must eventually give way to some hard realities of the human condition. As in any great drama, the central question is whether other, more vital values will be preserved.

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[125]Current proposals to provide catastrophic health insurance protection, *see, e.g.*, *Perspectives, Catastrophic Insurance*, Washington Rep. on Med. & Health, Apr. 21, 1986, would benefit from being examined in light of the concerns expressed herein about placing government in a central decisionmaking role.

The Lithotripsy Game in North Carolina: A New Technology Under Regulation and Deregulation*

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Robert S. McDonough***

I. The Stakes in the Game—Rewards of a New Technology

Every few years, it seems, an expensive new medical technology tests the ability of the health care system to assess its efficacy, safety, and cost-effectiveness and to allocate resources so that patients receive optimal treatment at reasonable cost. Resembling in this respect earlier diagnostic imaging technologies, extracorporeal shock wave lithotripsy (ESWL) is a recent technological breakthrough that has captured the attention of health planners and policymakers.[1] This noninvasive procedure, which employs equipment costing up to $2.7 million per installed unit, is revolutionizing the treatment of urinary stones.[2]

ESWL appears to be a highly desirable technology from every standpoint. Not only does it achieve excellent results with lower complication

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[1]For formal technology assessments of ESWL, see National Center for Health Services Research & Health Care Technology Assessment, U.S. Dep't of Health & Human Services, Extracorporeal Shock Wave Lithotripsy (ESWL) Procedures for the Treatment of Kidney Stones (1985); Office of Technology Assessment, United States Congress, Effects of Federal Policies on Extracorporeal Shock Wave Lithotripsy (1986); Farrell, *Percutaneous Ultrasound Procedures for the Treatment of Kidney Stones*, 1986 Int'l J. Tech. Assessment Health Care 152; Health and Public Policy Committee, American College of Physicians, *Lithotripsy*, 103 Annals Internal Med. 626 (1985). For other recent descriptions and evaluations, see Mueller, *Extracorporeal Shock Wave Lithotripsy of Ureteral Stones: Clinical Experience and Experimental Findings*, 135 J. Urology 831 (1986); Riehle, *Extracorporeal Shock Wave Lithotripsy for Upper Urinary Tract Calculi: One Year's Experience at a Single Center*, 255 J. A.M.A. 2043 (1986); Webb, *Extracorporeal Shock Wave Lithotripsy and Percutaneous Renal Surgery*, 58 Brit. J. Urology 1 (1986).

[2]In ESWL, electrohydraulic shock waves shatter kidney stones into small fragments so that they can be passed naturally by the patient. Chaussy & Schmiedt, *Shock Wave*

rates than invasive therapies,[3] but even given the high cost of "lithotripters," it may cost less per treatment than the surgical procedures it replaces.[4] Margaret Heckler, Secretary of Health and Human Services, called attention to both the medical benefits and the cost savings of ESWL when she announced the approval of the first lithotripter by the Food and Drug Administration (FDA) in 1984.[5]

Although there is virtually no question that ESWL is highly efficacious and extremely safe, it has created significant problems for the health care system. In particular, early and widespread recognition of the potential benefits of ESWL put intense and sudden pressure on those processes that society has installed to evaluate medical technology and to guide the health care system's development. State certificate-of-need (CON)[6] regulators were put in the position of being able to award very big prizes to a very few. Entrepreneurial urologists and hospitals, playing for large stakes, pushed the regulatory system very hard. In cases where the regulators stood firm, they were in the potentially awkward position

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Treatment for Stones in the Upper Urinary Tract, 10 UROLOGIC CLINICS N. AM. 743 (1983). Prior to the procedure, the patient is anesthetized to keep him pain-free and immobilized while shocks are administered. Finlayson & Thomas, *Extracorporeal Shock-Wave Lithotripsy*, 101 ANNALS INTERNAL MED. 387, 388 (1984). The patient is then placed into a tub of water over a shock-wave generator. A two-axis x-ray system is used to locate the stone and the shock-wave generator is adjusted so that the shock-waves are focused on the stone. Approximately 1300 shocks are administered during the average one-hour procedure.

A lithotripter currently costs approximately $1.7 million, not including the costs of installation, which can add an additional $1 million to the price. American Hosp. Ass'n, *Lithotripters: Noninvasive Devices for the Treatment of Kidney Stones*, 6 HOSP. TECHNOLOGY SERIES: GUIDELINE REPORT 15, 19 (1985). *But see infra* note 15 (stating that several U.S. companies are exploring the manufacture of lower cost lithotripters).

[3]Surgical lithotomy has an associated mortality rate of 0.8 percent, R. SMITH & D. SKINNER, COMPLICATIONS OF UROLOGIC SURGERY AND MANAGEMENT 102 (1976), whereas ESWL has a complication rate of less than one percent with virtually no associated mortality, Finlayson & Thomas, *supra* note 2, at 388.

[4]The primary cost saving of ESWL comes from a reduction in the length of hospital stay. *FDA Approves Lithotripter for Kidney Stone Shattering*, 253 J. A.M.A. 620 (1985) [hereinafter *FDA Approves Lithotripter*]. An uncomplicated surgical lithotomy requires an average stay of one to three weeks. Castaneda-Zuniga, *Nephrostolithotomy: Percutaneous Techniques for Urinary Calculus Removal*, 134 AM. J. RADIOLOGY 721, 724 (1982). The newer technique of percutaneous nephrolithotomy requires four to eight days of hospitalization. *Id.* ESWL patients currently remain in the hospital only three days on average, and it is anticipated that ESWL will eventually be performed on an outpatient basis. *FDA Approves Lithotripter*, *supra*, at 620-21.

[5]U.S. DEP'T OF HEALTH & HUMAN SERVICES, HHS NEWS 2 (Dec. 19, 1984) (statement by Margaret M. Heckler, Secretary of Health & Human Services).

[6]Certification of need is a legislatively mandated process whereby health care providers and institutions must obtain approval from a state agency before making large capital expenditures or instituting costly new services. *See infra* notes 12-15 and accompanying text.

of giving the winners valuable monopolistic franchises and depriving the losers of patients and significant income.[7] Where the regulatory system gave way, the possibility of overinvestment in duplicative facilities raised the specter of excessive costs, overuse of ESWL, and neglect of alternative therapies when they might be medically indicated.[8] Although ESWL is a striking development in itself, much of its interest for policymakers lies in the lessons it teaches about the overall health care system and its ability to allocate resources and accommodate technological change.

ESWL has had a particularly significant impact on urologic practice in North Carolina. That state lies in the center of the so-called "stone belt," an area of the country where urinary stones are particularly common.[9] North Carolina urologists are thus heavily committed to the treatment of urinary stones, devoting an estimated fifteen to twenty percent of their professional work to this condition.[10] Hospitals, too, obtain significant income from urinary stone patients, and this business has been widely shared by all hospitals. ESWL thus posed an economic threat to both urologists and hospitals in North Carolina. If treatment of stones in the kidney and upper urinary tract were suddenly concentrated in a small number of lithotripsy centers, the impact on the providers losing that business would be substantial. The appearance of this new technology in North Carolina also threatened to accentuate a flow of patients away from community hospitals into the state's few, but strategically located, academic medical centers. A major "town/gown" conflict thus quickly developed as community urologists sought to keep their patients out of the academic institutions, which allegedly did not always return patients to the care of their original doctors.

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[7]*See, e.g.*, *Michigan News Briefs*, United Press International, Feb. 11, 1986 (reporting that Michigan Department of Public Health had ordered Michigan's two largest hospitals not to bill patients for ESWL until they received CON approval); *New Kidney Stone Crushing Technique Studied*, United Press International, April 26, 1985 (stating that Virginia Health Commissioner announced his intent to "guard against unnecessary proliferation" of lithotripers despite the increasing number of applications for certificates of need for lithotripters).

[8]*See, e.g.*, Freifeld, *The Rush to Crush*, FORBES, March 11, 1985, at 170, 171 (stating that in Chicago, health planners had succumbed to provider pressures in approving more lithotripters than were necessary).

[9]*See* Brown, *Living in the Stone Belt Can Be Dangerous to Your Kidneys*, Durham Morning Herald, Jan. 13, 1987, at A9, col. 1. Apparently because of dietary factors, residents of southeastern states have a higher incidence of calculi of the kidney and ureter than other U.S. citizens. *Id.* In 1984, the incidence of kidney stones in North Carolina was 29.9 per 10,000 population contrasted with the mean incidence among states of 16.4 cases per 10,000 population. Sierakowski, *The Frequency of Urolithiasis in Hospital Discharge Diagnoses in the United States*, 15 INVESTIGATIVE UROLOGY 438, 440 (1978).

[10]Personal communication with John L. Weinerth, M.D., Associate Professor, Division of Urology, Duke University (July 1986).

Although the struggle to capture the North Carolina ESWL market is interesting in itself as a spectator sport, there are more important reasons to focus on the North Carolina experience. First, the operation of the CON system was tested in significant ways, yielding lessons for students of this form of regulation. Second, the method of paying urologists for lithotripsy received an unusual degree of attention, highlighted by a clash between practicing urologists and Blue Cross and Blue Shield of North Carolina (NCBCBS) over the proper professional fee. This controversy yields some lessons about how business is done in a state that has yet to see many of the vaunted benefits of competition in health care[11] and suggests some serious questions about the role of Blue Cross and Blue Shield plans in forestalling such competition not only in North Carolina but in the nation as a whole. Finally, the North Carolina story has recently culminated, for reasons that will appear, in the repeal of CON requirements for lithotripters, thus presenting everyone—but especially NCBCBS—with a future challenge. This Article thus includes a discussion of what must happen now in the deregulated North Carolina market (and wherever else deregulation is tried) if the right number of lithotripters are to be appropriately located and properly used. Although it is far from clear that North Carolina is ready for deregulation of a single technology of this kind, the lessons drawn from the North Carolina experience may suggest to other states the merits of general deregulation and the urgency of encouraging the competitive developments that would permit it.

II. The CON Game—Winner Take All

State CON laws were intended to contain costs and make the development of the health care system more rational by requiring prior state approval before major capital expenditures could be made and new health services could be introduced.[12] Because prevention of duplication

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[11] *See infra* notes 45-63 and accompanying text.

[12] *See, e.g.*, P. Joskow, Controlling Hospital Costs: The Role of Government Regulation (1981); D. Salkever & T. Bice, Hospital Certificate-of-Need Controls: Impacts on Investment, Costs, and Use 11-24 (1979); Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards and Procedures in Certificate of Need*, 1978 Utah L. Rev. 83, 84-90; Havighurst, *Regulating Health Facilities and Services by "Certificate of Need,"* 59 Va. L. Rev. 1143, 1155-69 (1973). Like other states, North Carolina has enacted a CON law, N.C. Gen. Stat. § 131E-175 to 191 (Supp. 1985), pursuant to the National Health Planning Resource and Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225, 2584-645 (codified as amended at 42 U.S.C. § 300k-n (1982)). An earlier North Carolina CON law was held invalid under the state constitution. *In re* Certificate of Need for Aston Park Hosp., Inc., 282 N.C. 542, 193 S.E.2d 729 (1973). Before creating the present statute, the state resisted, unsuccessfully, the subsequent federal compulsion to enact a CON statute meeting federal specifications. *See* North Carolina *ex rel.* Morrow v. Califano, 445 F. Supp. 582 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978).

is a key regulatory goal, these laws create a powerful incentive for providers to put any promising new technology, tried or untried, in place as quickly as possible; once CON approval is obtained, there is a strong regulatory barrier to entry by competitors until the market expands enough to support a second facility without appreciable harm to the first. Even if the first mover purchases costly first-generation equipment, it will be protected against competition from a later applicant offering to provide the same service for less.[13] The convoluted rationale for protecting inefficient providers from price competition in this way is not addressed here,[14] but it is notable that one effect of this form of regulation is to encourage early investment by relieving the proponent of the concern that his investment will be devalued when more efficient technology becomes available. This point is of present interest because other lithotripsy devices that are now under development are expected to cost substantially less than the devices currently being installed.[15]

North Carolina providers began jockeying for CON's soon after the announcement of plans for introducing the lithotripter into the United States from Europe, where it was first developed. Indeed, an application to offer ESWL in North Carolina was filed one month before Dornier-

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[13]*Cf.* C. HAVIGHURST, DEREGULATING THE HEALTH CARE INDUSTRY 195-202, 214-22, 345-53 (1982) (noting the protectionist tendencies of CON regulation with respect to such desirable cost-saving innovations as home health care, HMO's, and ambulatory surgical facilities).

[14]*Id.* at 277-85 (explaining and criticizing the thinking behind protectionist regulation).

[15]In addition to Dornier-System, the manufacturer of the first device approved in the United States, at least four U.S. companies are exploring the manufacture of lithotripters. The first of these to begin clinical testing was Medstone International, Spartanburg, South Carolina. As of May 1985, Medstone had obtained FDA investigational device exemptions for five sites. American Urologic Ass'n, *Report to the Executive Committee of the AUA: Ad Hoc Committee to Study the Safety and Clinical Efficacy of the Current Technology of Percutaneous Lithotripsy and Noninvasive Lithotripsy* 20 (May 16, 1985) [hereinafter *Report to the Executive Committee*]. The Medstone lithotripter uses a fluid-filled bag for the acoustic interface; with the Dornier device, the patient is placed in a tub. The estimated cost of the Medstone lithotripter is about $800,000, about half the cost of the Dornier device.

Two other firms have conducted *in vivo* studies in animals. International Biomedics, Inc., of Issaqua, Washington, uses a laser-driven shock wave generator and water-filled chest waders for the acoustic interface. *Id.* Another lithotripter, being developed by Dr. Fray Marshall and colleagues at the Johns Hopkins Medical Center, also uses a fluid-filled bag but differs from others in using ultrasound rather than x-rays for imaging. *Id.* at 21. The anticipated cost of the Hopkins device is between $250,000 and $500,000. The SD-3 lithotripter, being developed by Northgate Research, Inc., of Plattsburg, New York, was only in the *in vitro* investigational stage in 1985. *Id.* at 20. The cost of this device, if perfected, is estimated to be only $250,000.

Because lower cost second-generation devices may become available, hospitals may be hesitant about purchasing costly first-generation equipment. *See The Race for Competing Lithotripters Heats Up*, HOSPITALS, July 20, 1986, at 30; *Lithotripsy: Hospitals Take a Wait and See Attitude,* HOSPITALS, May 20, 1986, at 75.

System GmbH, the German manufacturer of the original lithotripter, filed its initial application for FDA approval of the device on February 22, 1984. This application—by North Carolina Baptist Hospital in Winston-Salem, which is associated with The Bowman Gray School of Medicine of Wake Forest University—was approved in June 1984, six months before the FDA approved the Dornier device.[16] A second application—by Carolina Lithotripsy, Ltd., a limited partnership of forty-two North Carolina urologists—was also filed before the FDA acted. This Fayetteville-based partnership was organized by Dr. William Jordan,[17] who had gone to Germany at an early date to learn the procedure and get a jump on the market when lithotripters finally became marketable in the United States.[18]

The forehandedness of these CON applications was impressive because FDA approval of a new technology normally takes several years.[19] However, in this case, the FDA, recognizing the potential benefits of the lithotripter and its extensive testing and use in West Germany, acted with extraordinary rapidity,[20] approving the device on December 19,

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[16]*See* Letter from William Vaughn, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to John Lynch, President, North Carolina Baptist Hospitals (June 29, 1984). Dr. David McCullough, Chairman of the Division of Urology at Bowman Gray School of Medicine of Wake Forest University, explained that Bowman Gray urologists decided to pursue CON approval early because they were aware of the results of ESWL testing in Europe and believed that ESWL's potential benefits made it the "wave of the future." Personal communication with David McCullough, M.D. (Jan. 1987).

[17]*See* Carolina Lithotripsy, Ltd., Certificate of Need Application 1-5 (July 12, 1984); *see also Big Lithotripter Venture Helps Out Small NC Hospital*, HOSPITALS, May 20, 1986, at 76 (discussing the Fayetteville, N.C., partnership of urologists that purchased a lithotripter to be installed at Highsmith-Rainey Memorial Hospital).

[18]Personal communication with William Jordan, M.D. (July 1985).

[19]Currently, the FDA estimates that the median approval time for devices since 1976 has been approximately 8-1/2 months. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSMETIC L.J. 510, 518 (1984). This median is misleading, however, as an indication of the review time for truly new devices. Approximately 60% of the premarket applications (PMAA's) received by the FDA are not for new devices but for devices regulated under transitional provisions applicable to devices formerly regulated as new drugs. *Id.* at 518 n.44 (citing 21 U.S.C. § 360j(1)(1) (1982)). The review time for these transitional devices, *e.g.*, sutures and contact lenses, is generally very short. *Id.* In addition, many PMAA's are returned to the sponsor for additional data, and this time is not counted in the FDA's statistics. *Id.* at 518. Economist Henry Grabowski, a student of drug and device regulation, believes that truly new medical devices will be subject to an average approval time approximately equal to that for new drugs. Personal communication with Henry Grabowski, Professor of Economics, Duke University (July 1985). The FDA has taken an average of 35 months following the filing of a new drug application (analogous to a PMAA) to approve new drugs. H. GRABOWSKI & J. VERNON, THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS 23 (1983).

[20]The FDA approved extracorporeal shock wave lithotripsy for general use less than one year after the commencement of clinical trials in the United States. This was unusually

1984.[21] Carolina Lithotripsy's CON for a lithotripter, scheduled to be located in a Fayetteville hospital, was issued one day later.[22]

Applications by other North Carolina providers followed quickly upon the first CON awards and the FDA action. Stone Institute of the Carolinas, a Charlotte-based partnership of urologists, applied for a CON in August 1984, and got its approval in January 1985.[23] North Carolina Memorial Hospital in Chapel Hill, an adjunct of the medical school of the University of North Carolina, received CON approval in May 1985.[24] Unsuccessful applicants included St. Joseph's Hospital of

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rapid action. *See supra* note 19. One commentator argued, however, that the FDA's approval of lithotripsy was not fast enough, and that the FDA's delay in approving lithotripsy caused many kidney stone patients, especially those who were high-risk surgical candidates, to suffer. Gieringer, *The FDA's Bad Medicine*, 33 Pol'y Rev. 71, 71 (1985).

One reason for the FDA's relatively speedy approval of ESWL was the extensive testing of the procedure in Europe before it was introduced in the United States. The FDA had agreed to base its approval largely on the European data. The FDA's National Center of Devices and Radiological Health will generally consider foreign data in support of premarket approval if the studies appear valid and if the rights, safety, and welfare of the research subjects were not violated. Shapiro, *Legal Aspects of Premarket Approval of Medical Devices*, 38 Food Drug Cosmetic L.J. 205, 211 (1983). Although the Center has not relied solely on foreign data in the past, the FDA has recently proposed to allow approval of new drugs based solely on foreign clinical data. *See* 47 Fed. Reg. 46,643 (1982). In an interview, attorney Joseph Onek, who represented Dornier-System in the FDA application process, said that testing centers in the United States were able rapidly to confirm the results of the extensive testing completed in Europe. Personal communication with Joseph Onek (July 1985). At the time that FDA began to evaluate the lithotripter, it had been used in Germany for five years. Gieringer, *supra* at 71. U.S. testing began less than one year prior to FDA approval. Nearly 2,000 of the 10,000 or so treatments worldwide had been performed in the United States. U.S. Dep't of Health & Human Services, *News Release*, HHS News 2 (Dec. 19, 1984).

Onek also explained that Dornier was slow in introducing the lithotripter to the U.S. market. By the time it was introduced, urologists, nephrologists, and others knew about the lithotripter and its advantages and were anxious to obtain the device. Another factor that may have led to more rapid approval of lithotripsy was the lower per-patient cost of the procedure. Onek was of the opinion that although relative cost-effectiveness is not an explicit criterion for approval, FDA officials were aware of and motivated by the lower costs associated with lithotripsy.

[21]Food & Drug Admin., U.S. Dep't of Health & Human Services, Summary of Safety and Effectiveness Data: Dornier Lithotripter, Model HM3 20 (1985).

[22]*See* Letter from Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to William Jordan, M.D., Partner, Carolina Lithotripsy, Ltd. (Dec. 20, 1984).

[23]*See* Letter from Jack Brinson, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources to Orion Finklea, President, The Stone Institute of the Carolinas, Inc. (Jan. 28, 1985).

[24]Letter from Nancy Bres Martin, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources to Jane Rhoe-Jones, Acting Director of Planning, North Carolina Memorial Hospital (May 30, 1985).

Asheville[25] and Duke University Medical Center in Durham;[26] the CON applications for both facilities were denied because other facilities were deemed sufficient to serve patients in their respective service areas.[27]

A fifth lithotripter slipped into the state through a crack in the regulatory defenses. A CON application by physician-owned Piedmont Urinary Stone Center, Inc. (Piedmont), which proposed the installation of a lithotripter in a Winston-Salem hospital, was reviewed together with the application of Bowman Gray's North Carolina Baptist Hospital. Piedmont's application was denied because only one service was deemed necessary in the Winston-Salem/Greensboro area and the CON agency preferred that such a service be associated with an academic institution.[28] Piedmont then proposed, however, to install a lithotripter in an outpatient facility unconnected with a hospital and successfully applied to the CON agency for a ruling that the CON statute did not apply to capital investments in major medical equipment to be installed in physicians' offices.[29] Although the legislature quickly moved to close this loophole by extending CON regulation to lithotripters "regardless of ownership or location,"[30] Piedmont's plans were unaffected, and its lithotripter is currently operating in Winston-Salem.

As in the comparative hearing pitting the Piedmont physician group against Bowman Gray's Baptist Hospital, the town/gown conflict was evident throughout the struggles over the provision of ESWL in North Carolina. The next two CON's went to physician groups that had filed their applications well before the other academic institutions. Subse-

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[25]Letter from Dudley Stallings, Project Analyst, and Susanne Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Les Brown, Director of Planning and Development, St. Joseph's Hospital (Aug. 27, 1985).

[26]Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, Required State Agency Findings, Disapproval of CON for Extracorporeal Shock Wave Lithotripter, St. Joseph's Hospital 2-3 (Aug. 27, 1985).

[27]Letter from Nancy Bres Martin, Project Analyst, and Robert Fitzgerald, Assistant Director, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to William Anlyan, M.D., Chancellor of Health Affairs, Duke University Medical Center (May 30, 1986).

[28]*See* Letter from Everette Jenkins, Assistant Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Keith Christian, President, CV, Inc. (July 17, 1984).

[29]*See* Declaratory Ruling, *In re* Request for Declaratory Ruling by Piedmont Stone Center, P.A., Piedmont Stone Joint Venture, and Carolina Medicorp., Inc. (Mar. 28, 1985); Letter from Jack Brinson, Project Analyst, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, to Charles Hauser, Agent, Piedmont Stone Center (Apr. 9, 1985).

[30]The amended statute required that all persons obtain a certificate of need prior to the acquisition of a lithotripter "regardless of ownership or location." N.C. GEN STAT. §§ 131E-176(16)g, 178(a) (Supp. 1985). On the policy implications of regulating capital equipment in physician offices, see C. HAVIGHURST, *supra* note 13, at 205-10.

quently, Memorial Hospital in Chapel Hill succeeded despite its presence in the same service area as the Fayetteville group, in part because it asserted educational and research needs.[31] (Duke, ironically, was unable to make this argument because it already possessed a lithotripter for research use, which was exempt from the CON requirement, and therefore sought only authority to offer a clinical service for compensation).[32] Perhaps in an effort to defuse opposition from community urologists, Memorial and Baptist hospitals made special arrangements whereby the former could obtain privileges to admit and treat ESWL patients. The claims of community urologists, asserted in a number of applications and challenges against the academic centers, included concern for the convenience of patients, the financial security of community hospitals, and the increasing dominance of the academic institutions.[33]

Although the CON regulators stood firm against exceeding a total of five lithotripters in the state, certain powerful interests were unhappy with the outcome of the CON process, which resulted in inconvenience for citizens in the western part of the state and left one prestigious institution (Duke) barred from charging for the use of a lithotripter already in place. Several legislators took up the cause of Duke and St. Joseph's Hospital in Asheville and explored the possibility of legislation that would bypass the CON agency. Because North Carolina, unlike some states, does not allow "special legislation" favoring named private interests,[34] it was necessary to write the exception in generic terms that bespoke a plausible legislative objective. In about two days' time, a bill was written and passed by the House of Representatives defining conditions for exemption that only Duke and St. Joseph's could meet.[35] Shortly thereafter, however, the Senate took a different view, and both

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[31]*See* North Carolina Memorial Hospital, Certificate of Need Application, Attachment 3, 5 (Dec. 11, 1985).

[32]*See* Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources, Required State Agency Findings, Disapproval of Conversion of Research Lithotripter to Clinical Use, Duke University, 6 (May 30, 1986).

[33]*See, e.g.*, Letter from Raymond Joyner, Chairman, Dep't of Urology, Durham County General Hosp., to Susanne G. Moulton, Chief, Certificate of Need Section, Division of Facility Services, N.C. Dep't of Human Resources (Jan. 31, 1985).

[34]*See* N.C. CONST. art. II, § 24; *cf.* Commissioner of Public Health v. Bessick M. Burke Memorial Hosp., 366 Mass. 734, 323 N.E.2d 309 (1975) (upholding constitutionality of exemptive legislation applied to CON); D. ALTMAN, R. GREENE & H. SAPOLSKY, HEALTH PLANNING AND REGULATION 28, 53, 186-87, 200-01 (1981) (discussing special legislation exempting named private interests from CON in Massachusetts).

[35]Oliver & Andrews, *House OKs Bill to Let Duke Use Kidney-Stone Machine*, Durham Morning Herald, July 2, 1986, at 1B, col. 2. Many other states have discovered that technocratic regulation of the health care industry frequently gives way whenever it becomes necessary to offend powerful interests that can effectively appeal to political leaders for assistance. *See* D. ALTMAN, R. GREENE, & H. SAPOLSKY, *supra* note 34, at 26-31, 153, 177-87, 202-10, 233-36 (noting ways providers circumvent the certificate of need process).

houses, in a surprising move, finally decided to repeal altogether the CON requirement for lithotripters and ESWL services.[36]

This sudden deregulatory move by North Carolina has somewhat startling implications. Many states, no longer bound by federally imposed requirements to maintain CON laws, have cut back on such regulation.[37] Although a few states have repealed their CON laws altogether,[38] most have maintained controls over large capital investments in hospital-based facilities, ostensibly on the theory that capital-intensive institutional services are least amenable to allocation by market forces.[39] North Carolina's deregulation of ESWL, which obviously was not the product of a well-considered policy judgment, is peculiar in that it preserves the basic scheme of comprehensive regulation but makes an exception for a technological development of the kind that most observers would agree is a prime candidate for regulatory allocation.

The North Carolina experience reveals once again the political dimensions and debatable premises of CON regulation. Despite numerous objective studies of the question, CON regulation has never been shown to control health care costs.[40] Indeed, substantial evidence suggests that CON laws were put in place not primarily to control costs but to protect the most powerful existing institutions against competitors skimming profitable business[41] and to legitimize rapidly rising costs in the eyes of

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[36]*See* Lineberry, *Duke Lithotripter Use Gets Senate Approval*, Durham Morning Herald, July 12, 1986, at 1C, col. 5. Because North Carolina had not contracted with the federal government under section 1122 of the Social Security Act, 42 U.S.C. § 1320a-1 (1982), to perform planning services, leading to possible denial of Medicare reimbursement of capital costs, this legislative action removed all governmental constraints on the installation of lithotripters.

[37]Simpson, *Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*, 19 IND. L. REV. 1025 (1987).

[38]*Id.* at 1061, 1079-81.

[39]*See* C. HAVIGHURST, *supra* note 13, at 4-5. In the National Health Planning and Resources Development Amendments of 1979, Congress identified the provision of "inpatient health services and other institutional health services" as being particularly subject to the market failure that it viewed as necessitating CON regulation for new health facilities and services. Legislative findings accompanying the 1979 amendments stated that "the prevailing methods of paying for health services by public and private health insurers" make competition an unreliable allocative mechanism and singled out institutional services as most likely to be among those "for which competition does not or will not appropriately allocate supply." 42 U.S.C. § 300k-2(b)(i)-(2) (1982); *see also* H.R. Rep. No. 190, 96th Cong., 1st Sess. 51-54 (1979).

[40]*See generally* C. HAVIGHURST, *supra* note 13, at 63-74 (summarizing analytical and descriptive studies of CON's effect on costs); P. JOSKOW, *supra* note 12, at 138-68; Sloan, The Track Record of Certificate-of-Need Programs (paper presented at the third annual Health Policy Symposium, "The Role of Health Planning in a Competitive Environment," Vanderbilt University, May 15-16, 1986).

[41]"In North Carolina, improvement of the borrowing capacity of the hospitals—by protecting them from competition—was an explicit purpose" behind the enactment of the state's first CON law. Havighurst, *supra* note 12, at 1164 n.77 (citing Durham Morning

an increasingly concerned public.[42] Moreover, some have argued that the main effect of entry regulation has been to protect payers and providers from having to alter their traditionally nonadversarial relationships by embarking, respectively, on prudent buying and competitive selling of health services.[43] North Carolina's deregulation of lithotripsy suggests that legislative support for CON regulation is weakening and that the public is running out of patience with a regulatory scheme that protects established institutions.

The natural question that arises is what happens next in North Carolina. Unless the market conditions that were deemed to warrant CON regulation have changed or can now change readily, there may be a proliferation of unneeded, overutilized lithotripters. According to the scenario visualized by advocates of health planning and CON regulation, the public can expect to pay a high price and receive inappropriate, even unnecessary, medical care. Whether this vision will be fulfilled, however, depends upon those who pay for medical care and their willingness and ability to defend themselves against the predictable higher costs. Later discussion, following examination of payment issues that have already arisen in North Carolina, will consider what actions payers might take in this regard and the actual prospects for their taking them.[44] That discussion will also consider whether the scenario may instead fulfill the predictions of deregulation advocates, who argue that unlimited entry will trigger prudent purchasing and effective price competition among providers, creating a market deterrent to replace the barrier that CON regulation supposedly erected to the creation of technological overcapacity.

III. Playing for Money

The active pursuit of CON's for ESWL facilities in North Carolina indicated that providers, particularly physicians, anticipated that the

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Herald, June 25, 1971, at 1C, col. 1). *See also* Payton & Powsner, *Regulation through the Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 Mich L. Rev. 203, 255-56 (1980).

[42]Payton & Powsner, *supra* note 41, at 247-48. This source shows that the main proponents of CON regulation were not themselves interested in cost containment but stood to gain if the public could be satisfied that continued cost escalation was justified. They may even have anticipated the great political difficulty encountered by public regulators in saying "no" to "needs" asserted by reputable providers. *See supra* note 35; C. Havighurst, *supra* note 13, at 25-52.

[43]The crucial observation of Payton & Powsner, *supra* note 41, is that CON laws perpetuated a financing system that served the interests of the dominant payers and providers. *See also* Havighurst, *supra* note 12, at 1156 ("Viewed in the light of possibilities for more fundamental changes in the market for insurance and health services, certificate-of-need laws may appear as conservative measures, designed to preserve the very institutions which create the problems to which they are addressed.").

[44]*See infra* notes 76-127 and accompanying text.

ESWL game would be highly profitable. However, what profits would be earned and to whom they would accrue would depend upon numerous factors, beginning with the policies and practices of the various payers and their ability to bargain for favorable rates of payment. The North Carolina experience featured a heated controversy over physician fees for lithotripsy as NCBCBS attempted to take a stand against the urologists' proposal that they receive an allowance for their services roughly equal to what they previously received when kidney stones were managed surgically. As explored further below, both the unusual effort made by NCBCBS and its failure to affect fees significantly are instructive.

The North Carolina experience with lithotripsy also focused attention on the economics of patient referrals from community physicians to ESWL centers. Although questions were raised about the ethical propriety of fees paid—ostensibly for follow-up services—by some centers to referring physicians, the discussion below shows that such payments may not be incompatible with fair play and appropriate outcomes in the lithotripsy game.

A. The UCR Game—with the Blues' Chips

When ESWL was first undertaken in North Carolina in 1985, NCBCBS had to set some limit on the urologists' professional allowance for the procedure.[45] Hospitals would be reimbursed their costs under the customary arrangement, but a limit on reimbursable physician fees had to be initially established by fiat because there was no "going rate" from which NCBCBS could derive a "usual, customary, and reasonable" (UCR) rate. Because no fee was yet either "usual" or "customary," NCBCBS turned to its Physician Advisory Committee for guidance on what would be "reasonable."

Largely on the strength of testimony by David F. Paulson, M.D., chief of the Division of Urology at Duke, NCBCBS's advisory committee determined that a fee in the range of $350 to $450 would be proper.[46]

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[45]Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Jan. 1987). *See also* MEDICAL ADVISORY PANEL OF THE HEALTH BENEFITS MANAGEMENT DIVISION, BLUE CROSS & BLUE SHIELD, FINANCIAL ANALYSIS OF EXTRACORPOREAL LITHOTRIPTER SERVICES, at .05 - .07 (discussing appropriate professional fee for ESWL). Under the typical NCBCBS contract, the patient patronizing a "participating" physician is assured that the physician will accept the plan's payment to him as payment in full (subject to any deductible or co-payment provided for); the plan's contract with the physician so provides and also sets a "UCR" limit on what the plan will pay. If the patient patronizes a "non-participating" doctor, the plan typically does not pay the physician directly but instead reimburses the patient for bills incurred up to a contractually specified limit (usually based on the UCR formula). *See generally* BLUE CROSS & BLUE SHIELD ASS'N, USUAL, CUSTOMARY AND REASONABLE: AN EXPLANATION FOR DOCTORS 1-3; BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, COST CARE: A PARTICIPATING DOCTOR PAYMENT PLAN (1985).

[46]Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Jan. 1987).

This amount was considerably less than the customary surgical fee of $1,500 to $2,000 for an uncomplicated nephrolithotomy, which Carolina Lithotripsy proposed to charge.[47] The higher fee would accord with the general position taken by the ad hoc committee on lithotripsy of the American Urological Association (AUA).[48] This committee was then chaired, coincidentally, by another North Carolinian, William H. Boyce, M.D., former chairman of the Division of Urology at Wake Forest's Bowman Gray School of Medicine.[49] Obviously, Dr. Paulson had taken a position very much at odds with the interests of his professional colleagues in the state.[50]

On the merits of the fee issue, the AUA's view was that the urologist is required to possess special knowledge and to exercise special skills in ESWL and that the pre- and post-procedure responsibilities associated with ESWL are the same as with surgery.[51] In the contrary view of Dr. Paulson, the urologist's role in ESWL is merely to supervise the technician, a much less demanding and extensive service than a surgical procedure.[52] Adopting the latter view and recognizing that some additional charges for services before and after the procedure might also have to be paid, NCBCBS initially recognized $450 as the limit of its payment responsibility for the procedure itself. In response, Carolina Lithotripsy

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[47]Personal communication with William Jordan, M.D. (July 1985). One urologist noted, however, that the professional fee for ESWL is only one element of the total charge and that the relative size of the professional fees among providers may not correspond to the relative total price for the procedure. Personal communication with David McCullough, M.D., Chairman of the Division of Urology at Bowman Gray School of Medicine of Wake Forest University.

[48]David McCullough, Chairman of the American Urologic Association Ad Hoc Committee on ESWL and Chairman of the Division of Urology at Bowman Gray School of Medicine, explained that the larger fee was also justified by the high cost of training urologists to perform lithotripsy. Personal communication with David McCullough, M.D. (Jan. 1987). For example, he estimated that the cost of training five Bowman Gray urologists to perform lithotripsy, including forgone earnings, was $100,000.

[49]American Urologic Association, Summary and Recommendations of the Meeting of the Ad Hoc Committee to Study the Safety and Clinical Effectiveness of the Current Technology of 1) Percutaneous Lithotripsy, and 2) Non-Invasive Lithotripsy 5 (May 9, 1984) [hereinafter AUA Summary and Recommendations]. The Ad Hoc Committee is currently chaired by North Carolinian David McCullough, M.D., who is also Chairman of the Division of Urology at Bowman Gray.

[50]Paulson stated that colleagues told him of the anger many urologists, particularly those in North Carolina, had toward Paulson for his stand on this issue. Personal communication with David Paulson (Nov. 1986). Paulson beleives that some urologists may have retaliated, but believes they were too "shrewd" to make such retaliatory actions obvious. *Id.*

[51]See AUA Summary and Recommendations *supra* note 49 at 5; American Urologic Ass'n, Ad Hoc Committee to Study the Safety and Clinical Efficacy of the Current Technology of Percutaneous Lithotripsy and Noninvasive Lithotripsy 14, 16-17 (May 16, 1985).

[52]Personal communication with William De Maria, M.D., Medical Director, NCBCBS (Jan. 1987).

declared its intention to bill NCBCBS-insured patients for the balance of the full fee.[53]

Sadly, NCBCBS could not hope to carry the day for several reasons. First, like most other Blue Shield plans, NCBCBS was committed in its contracts with subscribers to pay up to the UCR limit. To NCBCBS, this meant that, once the procedure had been billed for in a sufficient number of cases, it would have to step up its allowance to whatever had become "usual" for the particular provider and "customary" in the community. Although the plan might still challenge a fee as being unreasonable, a plan official at one point gave the impression that the plan did not regard "reasonableness" as an independent check on usual and customary charges.[54] At another point, this official expressed doubt that the unreasonableness of the allowance demanded by the urologists could be established, because other insurers around the nation were paying it.[55] In making this excuse, however, plan officials still seemed to assume that reasonableness is to be judged by what others do, not by objective economic criteria.

A second reason why the NCBCBS effort was unlikely to succeed was the unlikelihood that price competition by providers during the short period when the low limit on NCBCBS coverage was in effect would yield price reductions or reliable yardsticks for future payments. Even if patients, faced with paying the excess over NCBCBS's allowance, had known enough to seek out a lower-cost provider, no service area had more than one provider during the crucial period. In addition, providers would have known that the UCR level would jump dramatically if they could resist for only a short time the temptation to compete.

Finally, NCBCBS officials were unwilling to force a showdown over ESWL fees because they feared that such a challenge would induce urologists across the state to refuse to join NCBCBS's participating-physician program.[56] Ironically, NCBCBS's concern over attracting physicians to this program undercut the program's ostensible cost-containment objective, which was to be achieved by inducing physicians not to balance-bill subscribers. In this instance, plan officials' desire to make the program a success in terms of participation effectively prevented them from vigorously negotiating with physicians over an important cost item. Of course, the plan may have sensed accurately that no urologists (other than perhaps those at Duke, which may have higher costs in

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[53]Personal communication with William Jordan, M.D. (July 1985). This meant that the physicians associated with Carolina Lithotripsy would not "participate" in NCBCBS and that their patients would therefore not be protected from "balance billing." *See supra* note 45.

[54]Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Nov. 1986).

[55]Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987).

[56]*Id.*

other respects) would agree to participate at the lower rate and that balance billing would not trigger price shopping and effective price competition in the highly concentrated ESWL market.

Because the NCBCBS effort was doomed from the outset, the gesture that it made—difficult as it was for the plan officials concerned[57]—must strike an outsider as a pathetic demonstration of how ineffectual Blue Cross and Blue Shield plans generally are in challenging providers on economic issues.

The NCBCBS experience with lithotripsy fees also reveals the basic fallacies of the UCR method of setting reimbursement limits.[58] Essentially, the idea behind UCR is not, despite appearances, that market-determined prices can serve as a yardstick of what a proper allowance might be; there is in fact no pretense that only market-determined (as opposed to insurer-reimbursed) fees are considered in setting UCR limits. Instead, the premise underlying a UCR fee ceiling is simply that the great majority of physicians, as ethical practitioners exercising professional discretion, do not charge unreasonable or unconscionable prices and that it is therefore necessary only to compare a physician's fee with those of his peers to discover its reasonableness. Only a minute's reflection reveals how completely this conception of how professional services should be priced embodies the ideology of organized medicine, with its strong opposition to any arrangement inviting price competition among physicians. It is apparent then how NCBCBS, like other Blue Cross and Blue Shield plans that have followed similar policies, serves the interests of a medical cartel.[59] Only an insurer that had been bred specifically—as Blue Shield plans were[60]—for the purpose of advancing physicians'

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[57]Plan personnel viewed themselves—with some justification—as being courageous in taking on the urologists and indicated that they would probably not have been able to do as much as they did had Dr. Paulson, a respected physician, not come forward as an ally. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (July 1985). One plan official stated that the allowance for ESWL was finally set at an amount equal to NCBCBS's average for an open surgical procedure. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987). This allowance was viewed as an accomplishment because it is 10% to 25% less than urologists' actual stated charges for lithotripsy. *Id.* However, this allowance is obviously far in excess of that which NCBCBS sought.

[58]*See* Crump & Maxwell, *Health Care, Cost Containment, and the Antitrust Laws: A Legal and Economic Analysis of the* Pireno *Case* 56 S. CAL. L. REV. 913, 915-18 (1983) (description and defense of the UCR method of payment); Roe, *The UCR Boondoggle: A Death Knell for Private Practice?*, 303 NEW ENG. J. MED. 41 (1981) (stating that the UCR concept has failed to control escalation of medical costs because it contains none of the limits applied to other services covered by insurance).

[59]*See infra* text accompanying notes 100-21.

[60]*See, e.g.*, ANDERSON, HEALTH SERVICES IN THE UNITED STATES 121-32 (1985) (explaining that Blue Shield plans were sponsored by state and county medical societies); BUREAU OF COMPETITION, FTC, MEDICAL PARTICIPATION IN CONTROL OF BLUE SHIELD AND CERTAIN OTHER OPEN-PANEL MEDICAL PREPAYMENT PLANS (Staff Report and Proposed

economic interests could maintain that the UCR system is a responsible way to disburse the public's money to physicians.

The long survival of the UCR method for "controlling" physician fees might suggest that consumers approved the ideology supporting the practice of using nonmarket rather than market mechanisms for procuring medical services. A closer look, however, reveals that because of ethical and legal restraints imposed on contract and corporate practice[61] and the resistance of provider cartels to those payers who sought to buy provider services on competitive terms,[62] consumers were rarely offered any alternative. Although recent years have seen the growth of such alternatives as health maintenance organizations (HMO's) and so-called preferred-provider organizations (PPO's), traditional payment mechanisms remain dominant in North Carolina.[63] The recent experience with lithotripsy fees provides an example of the high cost that consumers bear as a consequence. As discussed below, this experience, which is far from an isolated instance, demonstrates the burdens that providers and Blue Cross or Blue Shield plans, acting together, impose on consumers.

B. The Doctors Split Their Winnings

In another expression of its concern about cost containment, NCBCBS at one point declared its opposition to payments by lithotripsy centers to physicians merely for referring patients for treatment.[64] Although these payments were represented as being fees for follow-up services, NCBCBS personnel feared that the fees paid to the referring physicians were in fact unethical fee splitting—that is, rebates or kickbacks paid for procur-

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Trade Regulation Rule, April 1979) (describing historical origins of Blue Shield plans as creatures of state and local medical societies).

[61]In American Medical Ass'n v. FTC, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982), the court enforced an FTC decision condemning professional societies' ethical prohibitions on "contract practice"—that is, physicians contracting with lay-controlled intermediaries that might be viewed as retailing professional services to the public. Common-law and statutory restrictions on corporate intermediation in the doctor/patient relationship have also interfered with the ability of consumers to employ a sophisticated agent to select health care providers and bargain with them on consumers' behalf. *See, e.g.*, Att'y Gen. Op. No. 81-1004 (Calif., April 7, 1982); Rosoff, *The "Corporate Practice of Medicine" Doctrine: Has Its Time Passed?*, HEALTH LAW DIGEST, Dec. 1984, at 1 (Supp.).

[62]*See, e.g.*, Havighurst, *Professional Restraints on Innovation in Health Care Financing*, 1978 DUKE L.J. 303, 306-19.

[63]*See infra* notes 119-20; *see also* Conn, *Health Maintenance Organizations Arrive in North Carolina*, N. C. INSIGHT, Feb. 1985, at 58, 62 (noting that there were 36,600 enrollees in North Carolina HMO's in January 1985).

[64]Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (July 1986).

ing the patient's business for the center.[65] NCBCBS later accepted urologists' assurances that appreciable services were indeed being provided following treatment with ESWL.[66] At least one physician receiving such a fee viewed it as a payment for the referral, however.[67] In any event, the practice has not been discontinued.[68]

The medical profession has long regarded fee splitting as an unethical practice, and it has been the object of attention by licensing authorities and professional associations concerned with professional conduct.[69] A primary concern has been that rebates will distort a physician's professional judgment in referring a patient to a specialist, causing either referrals for unnecessary care or the selection of a specialist on a basis other than exclusive concern for the patient's welfare. The issue is more complex, however, than it first appears, and indeed it is possible that a referral fee may actually improve the chances that a patient will get optimal treatment. Without such an inducement to refer the patient, a primary physician may be tempted to provide a service himself rather than allow another more qualified or better equipped physician to earn the fee.[70] In the case of a patient with a kidney stone, for example, a physician might be induced to exaggerate his doubt about how the case should be managed and then to resolve such doubt in favor of medical management or surgery rather than referral for ESWL. As economist Mark Pauly has observed, prohibitions on fee splitting may leave the

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[65]Plan personnel had two concerns about payments for follow-up services to a referring physician for "post-procedure" care. First, they sought assurance that this payment was not merely a referral fee but was for care actually provided. Second, they wanted to ensure that patients had full knowledge of these fee arrangements. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Jan. 1987).

[66]*Id.*

[67]Personal communication with John Weinerth, M.D., Associate Professor of Surgery, Duke University Medical Center (July 1986).

[68]NCBCBS, in paying the physician's charge or reimbursing a patient for a cost incurred, had no easy way of knowing whether the physician was splitting the fee with another physician. NCBCBS did, however, refuse to reimburse the portion of the lithotripsy professional fee designated for "after care" by the primary urologist unless such care was actually provided. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Aug. 1986).

[69]*See, e.g.*, AMERICAN MEDICAL ASS'N, PRINCIPLES OF MEDICAL ETHICS § 6.03 (1982); 53 Ops. Cal. Att'y Gen. 117, 118 (1970) (interpreting the California prohibition). The American College of Surgeons has adopted an interpreting statement explaining that it considers a form of fee splitting the practice of billing a patient a single fee for lithotripsy and then distributing a portion of the fee to the referring physician. *Regents Issue Statement on Fees for Lithotripsy*, AM. COLLEGE SURGEONS BULL., April 1986, at 21. The College stated that the charge for services and identity of the provider should be disclosed to the patient. *Id.*

[70]As the supply of physicians grows and primary physicians become less busy, they may feel greater pressure to keep patients rather than refer them to specialists. Pauly, *The Ethics and Economics of Kickbacks and Fee Splitting*, 10 BELL J. ECON. 344, 348 (1979).

patient no less dependent upon the primary physician's ethical ability to subordinate self-interest in making professional judgments.[71] In addition, Pauly notes that other forms of reciprocity — cross-referrals and conferral of other benefits—are practiced and are condoned or at least ignored by licensing and professional authorities. It is not clear that patients' interests would be adversely affected if fee splitting were permitted and openly practiced.[72]

From the perspective of NCBCBS and other, particularly governmental, third-party payers, fee splitting naturally appears as an instance of "fraud and abuse."[73] Assuming, however, that the treatment itself was needed and of acceptable quality, it is not clear why a payer should be concerned how the fee that it has agreed to pay is divided among providers. Although the willingness of the referral specialist to rebate a portion of his fee is a clear sign that the fee is excessive, there is no reason to expect that the fee would be reduced if fee splitting were prohibited. The irony here is that such rebates are a manifestation of price competition among specialists and proof that competition can yield substantial benefits to anyone who controls the selection of the specialist—something that traditional third-party payers have been reluctant to do. It is of course understandable why NCBCBS would be embarrassed by unjustified payments to referring urologists; such payments obviously come out of the excessive fees that NCBCBS has been unable to resist paying for the procedure. Nevertheless, efforts by NCBCBS and professional interests to suppress fee splitting would not serve to lower that fee or benefit consumers.

Indeed, it appears once again that the consumer's interest may lie in fostering, not suppressing, fee splitting. Although at first glance it may not seem to matter to consumers how physicians divide their excessive

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[71]*Id.* at 349; *see also* Schaffer & Holloman, *Consultation and Referral Between Physicians in New Medical Practice Environments*, 103 ANNALS INTERNAL MED. 600, 601 (1985).

[72]Tort law and possibly other legal remedies would presumably discourage the worst abuses. Also, if fee splitting were a known practice, patients would be on their guard, and some physicians might disclose their practice and share the savings with patients. Pauly, *supra* note 70, at 349.

[73]Indeed, section 1877(b)(1)(A) of the Social Security Act, added by the Medicare-Medicaid Anti-fraud and Abuse Amendments of 1977, expressly prohibits the receipt of "kickbacks," "bribes," and "rebates" made "directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title." 42 U.S.C. § 1395nn (1985) (Medicare). *See also id.* § 1396h(b) (Medicaid). In United States v. Greber, 760 F.2d 68 (3d Cir. 1985), the court held that this statute was violated if the fee was to induce the physician to use the service, even if the fee was also intended to compensate the physician for professional services. *See generally* Gebhard, *Lithotripsy Referral Fees: Medicare Fraud and Abuse?*, AM. COLLEGE SURGEONS BULL., April 1986, at 16.

profits, the matter is not so simple. If a primary physician expects a rebate for referring stone patients for ESWL, he is likely to increase his competitive efforts to attract such patients, offering price and other inducements that will lower his net return and confer benefits on consumers. Again as Pauly has observed, the medical profession's historic opposition to fee splitting represents, in some measure, a desire to suppress price competition among specialists and to remove the destabilizing effects of rebates in markets for primary care.[74] By the same token, consumers would probably be better off if fee splitting were acknowledged as a legitimate competitive practice. Indeed, competition in fee splitting could compensate in some measure for the failure of NCBCBS and other payers to force ESWL centers to compete for the opportunity to serve their insureds.

It would be claiming too much to suggest that the problem of obtaining optimal treatment for stone patients at a competitive price would disappear if fee splitting were tolerated. Questions would still exist concerning the incentives and professional integrity of referring physicians and the ability of patients or insurers to detect and thus deter physician abuse. Moreover, the high level of concentration in ESWL markets suggests that competition may not be effective in forcing ESWL fees down to truly competitive levels.[75] Finally, some of the competitive strategies employed by primary physicians to attract stone patients would undoubtedly involve wasteful nonprice inducements, adopted precisely because price competition is unavailing when patients are heavily insured. Despite these reservations, however, the problems uncovered in the existing system make it highly probable that efficient allocation of resources is more likely to be approached under open competition than under the conventional arrangements sponsored by NCBCBS and favored and fostered by organized medicine.

IV. The Coming Showdown—Buying and Selling ESWL Under the New Rules

North Carolina's deregulation of lithotripters prompts speculation about the outcome of the new lithotripsy game. Many bettors predict

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[74]Pauly, *supra* note 70, at 348. For other instances in which prohibitions of rebating served anticompetitive purposes, see Department of Ins. v. Dade County Consumer Advocate's Office, 492 So. 2d 1032 (Fla. 1986) (statute prohibiting rebates to consumers by insurance agents held unconstitutional); Owen, *Kickbacks, Specialization, Price Fixing, and Efficiency in Residential Real Estate Markets*, 29 Stan. L. Rev. 931, 949-55 (1977) (title insurer's rebates to brokers).

[75]Given the oligopolistic character of the ESWL market, the amount of the rebate is likely to become standardized through tacit collusion. *See infra* text accompanying note 91.

that North Carolina citizens will lose, incurring substantially higher costs without enjoying commensurate benefits. Although a consumer victory can be imagined, it remains to be seen whether the players fielded by consumer interests, particularly NCBCBS, will change their strategy and improve their performance enough to produce an outcome different from that envisioned by the oddsmakers.

A. Prospects for a Consumer Defeat

If payment systems retain the forms favored by NCBCBS and providers, North Carolinians face the prospect that they will have to pay in full the costs of purchasing and maintaining an excessive number of costly lithotripters. In a normal competitive market, consumers are benefitted, not harmed, by excess producer capacity. As sellers ignore their "sunk" costs—that is, those investments that cannot be recovered by withdrawing from the market—competition causes unit prices to fall below average total cost, giving consumers a bargain until equilibrium is restored by the withdrawal of some capacity.[76] Competitive conditions also deter the creation of inefficient overcapacity because a would-be investor could not expect to recover his investment in new facilities unless existing facilities were either inadequate or relatively inefficient. In health care, unfortunately, because traditional reimbursement mechanisms give patients little reason to shop for low prices, it has not been possible to count on competition to drive prices below average total cost and to discourage overinvestment. If would-be investors in North Carolina lithotripters currently believe that existing financing arrangements are not likely to change before they have recovered their capital outlays,[77] North Carolina consumers do indeed face unjustified higher costs as a consequence of deregulation.

Higher prices to North Carolinians may also result from other causes. If payment systems do not threaten now or in the near future to put competitive or other pressure on high-cost providers, a would-be investor

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[76]Under competition, prices tend to equal marginal cost, the cost of the last unit produced. With overcapacity, marginal cost includes no capital costs. On the other hand, if production is at full capacity, marginal cost includes the cost of the capacity that must be added to increase production. *See generally* P. AREEDA, ANTITRUST ANALYSIS ¶ 114-16 (3d ed. 1981).

[77]An issue arises concerning the period over which an investor can recover his investment. In North Carolina, ESWL providers have pressed to have NCBCBS reimburse hospitals for lithotripter depreciation on the basis of a two-year useful life; NCBCBS has argued for amortization over five years. Personal communication with Clifford Balin, Director of Professional Benefits, NCBCBS (Aug. 1986). NCBCBS has resolved the dispute. *Id.* Obviously, a longer period of payback increases the risk that market conditions, including insurer practices, will change in ways detrimental to providers and will thus discourage overinvestment in lithotripters.

has no reason to await the availability of a lithotripter less costly than the Dornier device. In addition, consumers cannot expect to enjoy across-the-board cost savings when lower-cost devices do appear; they would instead, under prevalent cost-reimbursement formulas, continue to pay the full depreciation costs of obsolete equipment.[78] Finally, the absence of effective price competition would also allow providers who are not reimbursed strictly on the basis of costs actually incurred—physicians, in particular—to charge prices well in excess of their costs. It has already been shown how UCR allowances in North Carolina represent excessive payments for professional services. The ability of physicians to overcharge for their role in ESWL reflects the noncompetitive conditions prevalent in that market. Unfortunately, unless changes occur in payment systems, eliminating CON-protected monopolies of ESWL may not bring prices down.

A proliferation of lithotripters might also trigger higher health care costs in the form of overuse of the devices to treat stone patients who could be managed satisfactorily at much less expense without resorting either to the device or to surgery.[79] Traditional payment systems offer only weak defenses against such overutilization. One theory supporting CON regulation was that supply could be curtailed to an extent that

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[78]The Medicare program's position regarding capital costs is very much in limbo at the moment, contributing substantially to the uncertainty facing would-be investors in North Carolina lithotripters. Currently, under Medicare's prospective payment system, capital costs (depreciation, interest, and return-on-equity for for-profit institutions) are not included as part of per-case payment rates, but are reimbursed at actual cost. *See* E. Power, Extracorporeal Shock Wave Lithotripsy and the Medicare Prospective Payment System 8, 14 (1985). Because hospitals are assured coverage of the acquisition costs, hospitals are encouraged to acquire new technologies. *Id.* at 19.

However, the Reagan Administration has proposed a plan to phase Medicare capital payments into DRG's over a four-year transition period, beginning with fiscal year 1987 cost reports. Firshein, *HHS Capital Plan Arouses Provider Anxieties*, Hospitals, June 20, 1986, at 24 [hereinafter *HHS Capital Plan*]. Payments would be based on hospital-specific and national rates, with fiscal year 1983 cost reports trended forward. Firshein, *Providers Call '87 PPS Increase 'Unacceptable'*, Hospitals, July 5, 1986, at 31.

Meanwhile, hospitals and other providers are urging Congress to intervene. *Id.* Senator David Durenberger (Rep.-Minn.) has proposed a plan to fold Medicare capital payments into DRG's over a seven year period. *HHS Capital Plan*, *supra*, at 24. In addition, both the House and Senate have approved a supplemental appropriations bill that includes a one-year moratorium on inclusion of capital costs. *Hospital Shouldn't Wait to Evaluate Medicare Changes for Fiscal Year 1987*, 4 Prospective Payment Survival 108 (1986).

[79]Even though efficiency considerations may dictate using ESWL in many cases if overcapacity already exists, new capital investments enabling the provision of ESWL in identical cases would not necessarily be indicated. This anomaly results because, if the capacity is not already in place, the marginal cost of additional treatments, which must be compared to the advantages of ESWL over alternative therapy, includes the cost of new capacity and is therefore significantly higher than it would be if a lithotripter were standing idle. *See supra* note 76.

would force health care providers to ration limited resources to their best uses. Political conditions, however, have usually made it impossible for CON regulators to challenge medical opinion on appropriate utilization or to do more than try to prevent the creation of unused capacity.[80] Although CON regulation has therefore probably done little to contain the excess demand for services induced by passive insurance plans,[81] the lifting of CON restrictions, by removing the occasion for regulatory determinations of need, may have created some additional risk that physicians will extend their use of ESWL technology well beyond the point at which its benefits are at least equal to its cost of roughly $6,000 per procedure.[82] Lacking the ability to resist paying for all services that

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[80]*See* C. HAVIGHURST, *supra* note 13, at 36 (reporting an informal survey indicating that CON regulators see their role only as preventing duplication, not as forcing rationing).

[81]*See* references cited note 40 *supra*. *See also* C. HAVIGHURST, *supra* note 13, at 58-63 (demonstrating graphically how "inflationary pressures [attributable to passive insurance plans] may, like a balloon, bulge out at another place even if growth in one direction is effectively prevented").

[82]Indeed, North Carolina urologists have already begun to suggest that the device is appropriately employed to treat stones that are small enough to pass (with some discomfort, to be sure) through the urinary tract. *E.g.*, Personal communication with John Weinerth, M.D., Chief of Urolithiasis Service and Associate Professor of Surgery, Duke University School of Medicine (July 1986). Elsewhere urologists are finding other possible uses for lithotripsy, including its use against gallstones. *See* Sauerbruch, *Fragmentation of Gallstones by Extracorporeal Shock Waves*, 314 NEW ENG. J. MED. 818 (1986). The procedure may also be useful against bladder and kidney tumors. *See* Russo, *High Energy Shock Waves Suppress Tumor Growth in Vitro and in Vivo,* 135 J. UROLOGY 626 (1986); *Shock Waves Being Used to Bombard Cancer*, Durham Morning Herald, Nov. 17, 1986, at 1B, col. 1.

The "need" for lithotripsy and indeed for most medical services is difficult to determine for several reasons. Most observers are much more comfortable in asking simply whether the service is at all beneficial than in judging whether beneficial treatment is appropriate by comparing benefits with marginal cost. Moreover, the variability of marginal cost noted *supra* notes 76 and 79 reveals that appropriateness may depend on the availability of unused equipment and not exclusively on medical circumstances. The resolution of the need question is also complicated by partisanship. In utilization review, providers tend to be liberal in defining the need for their own services. *See generally* Havighurst & Blumstein, *Coping with Quality/Cost Tradeoffs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6 (1975). In CON review, the "haves" tend to minimize need and the "have-nots" to exaggerate it.

One Duke physician has stated that the studies used by the North Carolina CON agency greatly underestimated the need for lithotripsy. Personal communication with John Weinerth, M.D., Chief of Urolithiasis Service and Associate Professor of Surgery, Duke University School of Medicine (Aug. 1986). The North Carolina Work Group Report, prepared by physicians and administrators, estimated that approximately 20% of renal stone patients would be lithotripsy candidates. *See* North Carolina Lithotripter Work Group Report (June 14, 1985). Weinerth argued, however, that recent unpublished reports from lithotripsy centers throughout the United States indicate that 85% of all renal stone patients would benefit from lithotripsy. Weinerth explained that certain types of patients that were previously thought ineligible for lithotripsy, such as pediatric patients, patients with bilateral stones, and patients with staghorn calculi, may be lithotripsy candidates. However, a study

physicians prescribe in good faith, traditional health insurers expose North Carolina consumers to yet another source of unjustified higher costs.

B. Available Defenses

If unjustified cost increases of the foregoing kinds are to be averted in North Carolina, insurers of ESWL must find ways of limiting the fees and charges they will pay and of ensuring that only justified services are provided. The defensive strategies available include writing insurance policies that restrict coverage of the procedure, limit the amount payable for it, or deny or limit coverage of the ESWL services of particular providers.[83] Vigorous implementation of these approaches would be inconsistent with the practices of traditional insurers, however, being more like the choice-limiting methods of HMO's, PPO's, and other alternative financing and delivery mechanisms. Because financing plans of the latter types enroll only a small fraction of insured North Carolinians,[84] cost escalation is highly likely unless fundamental changes occur in the coverage enjoyed by the great majority of citizens. The small increases in the overall cost of traditional health insurance that are attributable to the deregulation of lithotripters are unlikely in themselves to induce a significant shift to alternative health plans.

Perhaps the easiest cost-containment strategy for controlling overutilization of ESWL is a contractual limitation of the plan's obligation to pay for the service in the absence of specified medical indications. As a practical matter, however, such a contractual condition of coverage is difficult to administer. For example, enforcement of a provision denying coverage for the shattering of small stones below two millimeters[85]

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at Shands Hospital of the University of Florida estimated that even fewer renal stone patients would be lithotripsy candidates. *See* Memorandum from Shands Hospital to All State Health Planning Agencies (April 17, 1985). Shands Hospital was involved in the clinical testing of the lithotripter and thus was among the first to receive the machine. Weinerth explained that the Shands group may have been overly conservative in their estimate of the need for lithotripsy because they had no interest in having a large number of lithotripsy centers enter the market.

[83]For a general discussion of cost-control strategies available to private financing programs, see Havighurst & Hackbarth, *Private Cost Containment*, 300 N. ENG. J. MED. 1298 (1979).

[84]*See infra* note 120.

[85]*See* Drach, *Urinary Lithiasis*, in CAMPBELL'S UROLOGY 1123 (5th ed. 1986) (stating most urinary stones less than 5 mm will pass spontaneously and patients with small stones may be treated with pain relief and instructions about recovery of stone). *See also* Preminger, *The Current Role of Medical Treatment of Nephrolithiasis: The Impact of Improved Techniques of Stone Removal*, 134 J. UROLOGY 6, 6, 9 (1985) (stating that in a study of 103 consecutive stone clinic patients, only 2% of the patients on medical therapy required an operation for newly formed stones, whereas 58% to 69% required an operation for new stones before beginning medical treatment; noting that the cost of management is less than $1,000 per year).

would require either that the plan accept the physician's representation of the stone's size or that x-ray evidence be obtained before the procedure. Enforcement of an evidentiary requirement by denial of coverage would be unreasonable, however, unless the patient or the physician knew of it in advance. Not only are patients unlikely to be aware of such administrative details, but physicians may also be unaware or may refuse to cooperate, insisting that the insurer should accept either their representations of the facts or their clinical judgments concerning patients' needs. In a similar situation, Indiana dentists organized a concerted refusal to provide x-rays to dental insurers for cost-containment purposes. Although that conspiracy was held to be an antitrust violation,[86] individual refusals to cooperate with insurers are to be anticipated.[87] Urologists might well claim that individual cases differ so that medical necessity cannot be determined without a fuller medical inquiry. Consequently, given the burdens associated with coverage restrictions and their unpopularity with patients and providers alike, it appears improbable that the possibility of saving a few dollars on claims for ESWL will alone trigger adoption of these strategies by North Carolina insurers.

North Carolina insurers might bring unit prices and utilization under some control by increasing cost sharing by patients, by tightening limits on reimbursable fees, or by shifting to fixed-indemnity coverage. Each of these approaches would be aimed at reducing the insurer's exposure and increasing the consumer's financial stake in each transaction in the expectation that he will shop for care with cost considerations more prominently in mind. Consumers may not be happy, however, to accept these new responsibilities and increased financial burdens. Moreover, there is little reason to believe that consumers would be especially effective shoppers or that conditions conducive to price competition prevail in the market for ESWL. Although a fixed indemnity payment for ESWL would seem to be a sensible policy and one that a particular insurer could rather easily adopt, strategies of this kind have been freely available to all insurers for a long time but have rarely been employed. It is

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[86]FTC v. Indiana Fed'n of Dentists, 106 S. Ct. 2009 (1986).

[87]A legal issue would arise if a physician billed for a service he had rendered knowingly without complying with the preconditions of the patient's insurance. Although precedent is scanty, *cf.* Eisenberg & Rosoff, *Physician Responsibility for the Cost of Unnecessary Medical Services*, 299 N. Eng. J. Med. 76 (1978), such a negligent failure to meet the patient's needs would seem to open the physician to professional liability for damages equal to the amount of insurance reimbursement lost. However, even though a patient might thus successfully resist a suit to collect the physician's bill, an insurer would undoubtedly find it both awkward to deny the patient's claim and difficult to ensure that physicians were aware of its requirements and their applicability to particular patients. Nevertheless, some insurers have required patients to obtain either second opinions on the need for treatment or the insurer's prior authorization of coverage for such elective procedures.

unlikely that the deregulation of ESWL poses enough of a threat of cost escalation to prompt significant redesign of coverage along these lines.

The most practical and effective approach to cost containment in private health insurance would concentrate not on writing selective coverage of ESWL or shifting costs from the insurer to its insureds, but on excluding certain providers altogether from eligibility to provide covered services. This approach, however, would violate the principle of free choice of provider that is embedded in the standard coverage offered by NCBCBS and strongly favored by health care providers. Such exclusion would also violate North Carolina law, which permits insurers to cover the services of designated "preferred providers" on more favorable terms but prohibits an insurer from excluding providers completely from treating insured patients at the insurer's expense.[88] Thus, although the ability to exclude a high-cost or uncooperative provider altogether from plan coverage might allow an insurer to obtain even more favorable results, North Carolina insurers wishing to procure ESWL services for their insureds on favorable terms must employ the PPO mechanism.[89]

The potential value to consumers of letting the insurer act as a middleman in procuring hospital and physician services is powerfully demonstrated by the ESWL situation in North Carolina. If an insurer could deliver paying patients to a provider by designating it as either the exclusive or a preferred provider of insured services, the insurer could bargain for a fair price both from the hospital for use of the lithotripter and from the physician presiding over the procedure.[90] In addition, the insurer could seek providers' cooperation with its efforts to control overutilization. Conversely, an insurer, such as NCBCBS, that feels constrained to cover care at all centers on equal terms lacks the ability to steer patients away from a high-cost provider and therefore has no bargaining power.

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[88]N.C. GEN STAT. §§ 57-16.1, 58-260.5 -.6 (1985).

[89]On the PPO concept, see generally P. LINDSEY, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS: ANNOTATED BIBLIOGRAPHY ON PREFERRED PROVIDER ORGANIZATIONS (1986); E. ROLPH, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS (1986); E. ROLPH, STATE LAWS AND REGULATIONS GOVERNING PREFERRED PROVIDER ORGANIZATIONS: EXECUTIVE SUMMARY (1986).

[90]The practice of fee splitting, *see supra* text accompanying notes 73-75 suggests that price competition is indeed feasible if a payer is willing to influence insured patients to select the low-cost provider. NCBCBS claims that it has been able to negotiate with providers on the machine use fee. Under the plan's provider contracts, the professional fee is reimbursed at a UCR rate, but the facility fee is negotiated, taking into account the provider's costs. Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Aug. 1986). *See supra* note 77. Because NCBCBS does nothing to steer its insureds to lower-priced centers, however, its bargaining power is minimal.

Despite the theoretical potential for obtaining competitive terms from providers through hard bargaining, the small number of providers of ESWL makes the real-world prospects for effective bargaining problematic. In any oligopolistic industry, the danger exists that each of the few competitors will realize that any aggressive competitive move that it might make in search of a short-run advantage would simply cause its competitors quickly to follow suit, making all of them worse off in the long run. With this perception of their "interdependence," the oligopolists are each likely to refrain from competitive moves, producing essentially the same result as if they had agreed explicitly not to compete.[91] In addition to creating conditions conducive to tacit collusion, the small number of competitors in the market also facilitates explicit agreements in restraint of trade. Even if ESWL providers did not actually fix prices, they might well agree, tacitly or overtly, to eschew competitive contracting with insurers. It is highly probable that an insurer seeking a beneficial contract for ESWL services in a market with few sellers would encounter substantial resistance to its proposals.

In keeping with the prediction that a concentrated provider market is unlikely to be competitive, North Carolina HMO's reported before deregulation that they anticipated no success in obtaining lithotripsy on special terms for their patients. Deregulation of lithotripsy may have significantly improved the prospects for competitive bidding, however.[92] With deregulation, a payer may now shop not only among the five providers originally in the market, but also among providers who were previously barred from entry. Indeed, Duke, which already has a lithotripter and has signified a willingness to accept a small professional fee, may be a lower-priced source of treatment. Even if Duke turns out to be no cheaper overall or inadequately cooperative with insurers' utilization-control efforts, the possibility remains that an insurer, acting

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[91]On oligopolists' interdependence, see generally 6 P. AREEDA, ANTITRUST LAW ¶ 1428-36 (1986).

[92]The CON program previously hindered the efforts of payers to obtain lithotripsy at competitive prices. Dr. Lawrence Oakes, Medical Director for the Kaiser-Permanente plan in North Carolina, explained that if there are a number of providers of a medical service in a given area, Kaiser can award an exclusive contract to the lowest-cost provider. Personal communication with Lawrence Oakes, M.D. (June 1985). This type of bargaining, however, is impossible in a monopolistic situation. Dr. Samuel Warburton, Vice President of the Health America plan in North Carolina, reported that prior to deregulation, he was unable to negotiate a urologist's fee for lithotripsy that was close to what he believed to be a competitive price. Personal communication with Samuel Warburton, M.D. (June 1985). Since deregulation, the plan has obtained a more satisfactory price. Warburton explained that, with prices for ESWL as high as $12,000 per procedure, Health America has been able to obtain a $4,300 total fee for an uncomplicated renal stone procedure. Personal communication with Samuel Warburton, M.D. (Oct. 1986). Warburton said he anticipates that he may be able to bargain for a total fee of $2,500 in 1987. *Id.*

independently or in concert with others, could stimulate the entry of yet another, lower-cost provider by offering it a long-term contract as the exclusive or preferred provider of ESWL services to its subscribers. Armed with the threat to pursue this newly available strategy, an insurer should find existing providers more willing to bargain for its business. It is paradoxical but crucial that repeal of CON requirements can generate pressure for lower prices even if no new entrant actually materializes.[93] Potential competition is frequently more effective than actual competition in keeping prices down in concentrated markets.

Despite the foregoing theoretical possibilities for effective cost containment, NCBCBS has so far made no move to change its methods of purchasing ESWL,[94] and other insurers, with a smaller overall stake, are even less likely to take specific steps to control the costs of ESWL in a deregulated environment. The financing system thus remains, as it was before deregulation, an invitation to overinvestment in lithotripters. Because North Carolina payers lack the ability or the will to control overutilization of ESWL and to buy cheaply in an overstocked market, North Carolina consumers face the prospect of a costly defeat in the new phase of the lithotripsy game.

V. Making the Game Competitive

An informal survey following the 1986 deregulation of ESWL by the North Carolina legislature revealed no provider with plans to install a lithotripter in the state other than the seven original aspirants, each of which was finally successful in negotiating the regulatory/political path to market entry—four by obtaining CON's, one (Piedmont) by exploiting a statutory loophole for nonhospital-based equipment, and two (Duke and St. Joseph's) by getting legislative assistance.[95] It is a mistake to conclude, however, because deregulation failed to trigger a burst of new investment, that market forces are satisfactorily controlling ESWL costs in North Carolina. Instead, because seven lithotripters appear themselves to be too many to service the state efficiently, it can be observed that regulation itself failed to prevent the creation of excess capacity.[96] More generally, it can be suggested that CON regulation,

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[93]*Cf.* C. Havighurst, *supra* note 13, at 234-36 (discussing how allowing HMO's to build new hospital facilities without a CON stimulates not new hospitals, but greater willingness of existing institutions to bargain with HMO's).

[94]Personal communication with William DeMaria, M.D., Medical Director, NCBCBS (Nov. 1986) (stating that NCBCBS was contractually bound in its subscriber contracts to pay the UCR reimbursement to providers).

[96]*See supra* notes 16-36 and accompanying text.

[96]It seems appropriate to count the Duke and St. Joseph's lithotripters as entering the market under regulation, not deregulation. *See supra* notes 25-36 and accompanying text.

almost inevitably politicized, provides unreliable protection for consumer interests whenever the financing system creates a lucrative market opportunity for providers. But whatever the final conclusion concerning regulation's value,[97] North Carolina's ESWL experience underscores that the fundamental source of the problem of overspending on health care is the dominant system of financing services. Under regulation, that system created powerful incentives for North Carolina providers to overexpand ESWL and gave rise to pressures that were impossible for the regulators and the political system to contain or to resist. Following deregulation, the financing system's chronic inability to take advantage of what should be a buyer's market for ESWL leaves North Carolina providers free to create unneeded, inefficient capacity and to operate it profitably at the public's expense.

Health care financing in North Carolina is typical of that found in most other markets for health services. Although there are increasing reports of major outbreaks of competitive buying and selling of provider services in many places throughout the nation, traditional financing as found in North Carolina remains the norm, and truly independent and competitive systems remain exceptional.[98] Despite the hopeful signs of effective competition in some markets, the ineffectiveness of the dominant health insurance mechanisms in controlling the price and cost of all health services, not just ESWL, has been notable for so long that one must wonder whether the game being played was or is a fair one[99] and whether a fundamental change in its rules may be necessary.

A. Is the Game Rigged?—"Say It Ain't So, Joe!"

The historical failure of conventional health care financing systems to defend consumer interests invites attention to the possibility that some of the players whom the fans have been supporting against providers

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[97]Deregulation might be safer if prepared for in advance. Recent deregulation in Arizona and Utah is alleged to have triggered a burst of capital spending. *See Arizona Deregulation Spurs Growth in Medical Facilities*, AM. MED. NEWS, September 19, 1986, at 7 (Arizona is experiencing an "unprecedented growth" in health care facilities as a result of repeal of CON regulations for hospitals and nursing homes). Although no objective evaluations of these experiences (by persons other than the displaced planners and regulators themselves) have been done, there may be some reason for concern. For a full statement of the case for deregulation and strategies for achieving it, see generally C. HAVIGHURST, *supra* note 13.

[98]*See infra* notes 119-20.

[99]A major source of unfairness to consumers has been providers' success in establishing the rules of competition in the health care sector. *See, e.g.*, Havighurst, *supra* note 62 (discussing restrictions imposed by providers on insurers' freedom to control costs and the potential value of antitrust law in eliminating such restrictions). Blue Cross and Blue Shield plans are also implicated in providers' efforts to make and enforce the rules of the game. *See infra* text accompanying notes 104-09.

may not have been playing to win. Unthinkable as this hypothesis may seem, the failure of NCBCBS to defend effectively against providers of ESWL is not just an isolated collapse attributable to one plan's poor management and lack of skilled players. Other teams in Blue uniforms have also consistently failed to strive for a consumer victory, appearing instead to have joined with providers to rig the outcome. Not only did the Blues themselves perform badly in the cost-containment field, but, as the following discussion briefly explains, their policies were instrumental in handicapping HMO's and commercial health insurers—other teams on which consumers might have placed their bets.[100]

The reason why many Blue Cross and Blue Shield plans did not battle providers successfully for lower costs and prices is, quite simply, that favoring consumers over providers was usually not in their corporate interest. Even after Blue plans were no longer controlled by the dominant hospital and physician organizations that created them, they generally adhered to a business policy of respecting and even furthering the economic interests of their original sponsors.[101] Indeed, many Blue plans appeared to prosper in the ensuing years, not because they offered consumers good value in insurance products, but because of the close relationships they maintained with organized providers.[102] Together with

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[100]*See generally* Havighurst, *Explaining the Questionable Cost-Containment Record of Commercial Health Insurers*, in THE POLITICAL ECONOMY OF HEALTH CARE (H.E. Frech ed., to be published). The machinations of providers and Blue Cross and Blue Shield plans somewhat excuse the poor cost-containment record of commercial health insurers. Although numerous factors affect the supply of and demand for insurers' cost-containment services and although the issue is complex, Blue/provider alliances, many of them informal, explain why consumer cost concerns have not been effectively transmitted to providers in the marketplace. *Id.* For a recent and more positive (and conventional) view of the Blues, see Greenberg, *The Evaluation of Blue Cross in a Competitive Marketplace*, BUSINESS & HEALTH, Nov. 1986, at 44.

[101]Although the FTC's efforts largely ended direct physician control over Blue Shield plans, *see* BUREAU OF COMPETITION, *supra* note 60; FTC, Statement of Enforcement Policy, 46 Fed. Reg. 48,982 (1981), that control was already attenuated by the time the FTC acted. Blue Cross plans had gradually withdrawn from direct affiliation with state hospital associations somewhat earlier. It is most unlikely that providers would have released the Blue plans from their direct control without more compulsion if they had not anticipated that once independent, the plans, as nonprofit corporations, would continue to pursue pro-provider policies in their own self-interest. *See infra* note 102.

[102]Because the Blues, as nonprofit corporations, were more interested in maximizing their gross revenues and market shares than in maximizing short-run corporate profits, there was a solid basis for an enduring and mutually advantageous relationship with providers. Nonprofit firms have somewhat different incentives than for-profit firms. Managers are more interested in increasing their market shares than increasing profits because the manager's salary and prestige is more closely associated with firm size than with profitability. Frech & Ginsburg, *Competition Among Health Insurers*, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT AND FUTURE 175 (W. Greenberg ed. 1974). In non-profit firms, such as Blue Cross and Blue Shield, the desire for growth is even stronger because there are no profits to distribute or shareholders to object. *Id.* at 175, 184.

government-conferred tax and other benefits,[103] these relationships gave the Blues a substantial competitive advantage over actual and potential competitors.

The pattern of Blue/provider relationships over many years and in many markets was one in which the Blue plan and the dominant organization of hospitals or physicians each used its own market position in such a way as to preserve and strengthen the market position of the other. Mutual accommodation was assured through liaison and committee structures. Most importantly, the most successful Blue Cross plans generally enjoyed large discounts from the hospitals,[104] and Blue Shield plans almost universally received comparable concessions from "participating" physicians.[105] Because these concessions were granted by providers acting in concert rather than extracted by the Blues in competitive bidding,[106] they left providers in a position to function as a cartel vis-

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[103]For tax purposes, the IRS long exempted Blue Cross and Blue Shield plans as social welfare organizations. *See* I.R.C. § 501(c)(4) (1982). In the Tax Reform Act of 1986, however, Congress eliminated the tax exemption granted to Blue Cross and Blue Shield plans. *See* H.R. 3838, 99th Cong., 1st Sess. §1012 (1985). Commercial health insurers and other proponents of this reform contended that special tax treatment of Blue Cross and Blue Shield plans is inappropriate because the plans employ business practices of commercial insurers and are engaged in an inherently commercial activity. General Accounting Office, Health Insurance: Comparing Blue Cross and Blue Shield Plans with Commercial Insurers 8-10 (1986). The Blue Cross and Blue Shield Association contended that the exemption is warranted because the exemption permits Blue Cross and Blue Shield plans to cross-subsidize coverage to high-risk individuals and small groups. *Id.* at 9.

State law also often confers valuable advantages on Blue plans in the form of exemptions from premium taxes and special privileges with regard to direct contracting with providers.

[104]Adamache & Sloan, *Competition Between Non-Profit and For-Profit Health Insurers*, 2 J. Health Economics 225, 227-29, 240-41 (1983). The mean relative Blue Cross discount is four percent and ranges as high as 27 percent. *Id.* at 229. Large discounts frequently correspond to large market shares.

A commercial insurer unsuccessfully challenged a typical Blue Cross discount in Travelers Ins. Co. v. Blue *Cross*, 481 F.2d 80 (3d Cir. 1973). For an analysis of this case pointing out its relevance to this discussion, see Havighurst, *supra* note 100.

[105]The concessions usually take the form of acceptance of payments under the UCR formula as payment in full. *See supra* note 45. *See generally* Bureau of Competition, *supra* note 60 (describing Blue Shield payment arrangements and characterizing them as price fixing when the plan is under physician control). For a case in which physician organizations offered similar collective concessions to any payer that obtained the organizations' approval (presumably by refraining from unfriendly acts), see Arizona v. Maricopa County Medical Soc'y, 457 U.S. 332, 356-57 (1982) (doctors' agreement on maximum fees held unlawful price fixing under the antitrust laws).

[106]*See, e.g.*, Travelers Ins. Co. v. Blue Cross, 481 F.2d 80, 84 (3d Cir. 1973) (discounts "negotiated jointly" by hospital association). Restrictions placed by physician organizations on individual physicians directly contracting with unapproved insurers were condemned in American Medical Ass'n v. FTC, 638 F.2d 443 (2d Cir. 1980), *aff'd by equally divided Court*, 455 U.S. 676 (1982); *see also* Havighurst, *supra* note 62, at 336-42.

a-vis the Blues' competitors. Although most Blue plans could have obtained larger price concessions by using their buying power to destroy the provider cartel, doing business with it usually proved more advantageous, yielding the Blues a net cost advantage over their competitors that was both larger and more permanent than they could have enjoyed under competition; as long as the cartel was effective, HMO's and commercial insurers could get no concessions from providers at all.[107] Consumers were thus unable to obtain coverage from plans that purchased provider services on truly competitive terms.[108] The Blues' greatest commercial successes were therefore gained, not by efficient operation in a competitive market, but by cultivating provider cartels that inflated the costs of their competitors.[109]

Organized providers, for their part, were generally glad to cooperate with and even to subsidize their biggest customer as long as it adhered to cartel-protective policies and provided insurance coverage in forms that obviated provider price competition[110] and kept demand for hospital and physician services artificially high.[111] Although providers complained

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[107]Until very recently, non-Blue payers were unable to bargain with providers for price discounts or concessions of any kind. For a full discussion of provider-imposed restraints, including boycotts of plans that offended providers, see Havighurst, *supra* note 62, at 336-42. Many commentators are noting the changing character of today's health care market. *See, e.g.*, *Managed Care: Will It Push Providers Against the Wall?*, HOSPITALS, Oct. 5, 1986, at 66. The new pressures on providers to grant competitive discounts and to accept undesired cost controls result from a combination of circumstances, including antitrust enforcement against provider cartel behavior; state PPO legislation and PPO development; the increased cost-consciousness and aggressiveness of larger purchasers; increased competitiveness on the supply side of the market because of surpluses of both physicians and hospital facilities; government's example as a prudent purchaser of services; and realization in the private sector that government is not likely, as it threatened to do throughout the 1970's, to regulate private health care costs. Despite widespread observations of intensified competition, however, competition's potential has not yet been realized in every market, and indeed has probably not been fully realized anywhere.

[108]The perception that consumers freely chose Blue-style coverage, with free choice of provider, etc., in preference to other kinds of coverage is mistaken because alternative types of coverage were seldom offered with price tags reflecting the full cost advantage obtainable though limitations on choice and competitive purchasing. *See infra* note 111.

[109]For recent scholarship focusing specifically on exclusion of rivals by raising their costs, *see* Krattenmaker & Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price*, 96 YALE L.J. 209 (1986).

[110]Hospital cost reimbursement, payment of physicians under UCR and similar formulas, limited use of cost sharing, and guaranteed free choice of providers make consumers largely indifferent to price considerations, thus freeing providers to compete in other, cost-increasing ways.

[111]The Blues have systematically offered broader coverage than other insurers. This coverage benefits providers by giving broad scope to "moral hazard"—that is, insurance-induced demand and insensitivity to price. It has been hypothesized that the Blues squander much of their cost advantage over other carriers by writing coverage in forms most advantageous to providers. Frech & Ginsburg, *Competition Among Health Insurers*, in

from time to time about a Blue plan's practices, such complaints were usually not inconsistent with the existence of powerful Blue/provider alliances.[112] Even when a major confrontation occurred between a dominant provider organization and a Blue plan, the triggering event was usually a minor matter, hardly a sign that the plan had gone over entirely to the consumer's side.[113] Indeed, the Blue plan's disputed policy was usually inspired, not by the plan's own corporate initiative, but by the irresistible demand of a state insurance commissioner[114] or major customer.[115] For many years, virtually all cost-containment initiatives by Blue Cross and Blue Shield plans that were not exogenously compelled were carefully negotiated with the affected provider interests before being announced as a Blue victory on the consumer's behalf.

The action of NCBCBS in tying its own hands in the fight to get ESWL services for North Carolina consumers at competitive prices was therefore not atypical. Most Blue Cross or Blue Shield plans have similarly maintained payment systems that weaken consumers' incentive to economize while simultaneously eschewing the role of an aggressive purchasing agent procuring providers' services for consumers at competitive prices.

COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 210, 216-19 (1978). This insurance is overbroad (inefficient) in the sense that few consumers would buy it if its added costs, instead of being subsidized by providers, were reflected in its price relative to alternative coverage. The result of inefficient insurance is an overallocation of societal resources to health care.

[112]One should not attach undue significance to complaints about NCBCBS practices that emanate from provider camps; within any conspiracy in restraint of trade, there are always differences of opinion, sometimes serious ones, over the best collective strategy. Thus, complaints and even lawsuits challenging plan practices by individual providers are to be expected even if the Blue plan is faithfully serving cartel interests. Conceivably, even such striking cases as Kartell v. Blue Shield, 749 F.2d 922 (1st Cir. 1984) (unsuccessful challenge to a plan's alleged monopsonistic exploitation of physicians), *cert. denied*, 105 S. Ct. 2040 (1985), and Ball Memorial Hosp. v. Mutual Hosp. Ins., Inc., 784 F.2d 1325 (7th Cir. 1986) (unsuccessful challenge to a Blue Cross-sponsored PPO as an exercise of monopsony power against hospitals), may involve only a difference of opinion concerning the best strategy for pricing provider services under emerging market conditions rather than the Blue plan's permanent defection from the old alliance. *But see* sources cited in note 117 *infra*.

[113]In *In re* Michigan State Medical Soc'y, 101 F.T.C. 191 (1983), a state medical society threatened a Blue plan with a statewide physician boycott because the plan attempted to control the cost of vision and hearing care. The medical society's vigorous and seemingly disproportionate reaction was prompted, not by the particular initiative itself, but by the Blue plan's unprecedented departure from the principle of free choice of physician. *Id.* at 216-21.

[114]In Kartell v. Blue Shield, 749 F.2d 922 (1st Cir. 1984), *cert. denied*, 105 S. Ct. 2040 (1985), the plan's refusal to allow balance billing was in part a function of state legislation and regulation.

[115]In *Michigan State Medical Society*, the initiative of Michigan Blue Cross and Blue Shield that was so offensive to physicians was dictated by the auto companies and the United Auto Workers. 101 F.T.C. at 216-21.

Although there have recently been some impressive departures by Blue plans from such pro-provider practices,[116] these defections have almost always occurred only because other prepayment mechanisms, primarily HMO's and PPO's, had already breached the defenses of the hospital and doctor cartels in the particular market. Facing price competition from efficient purchasers for the first time, the Blues had little choice but to abandon their old strategy and turn on their old allies.[117] Despite these notable breakdowns of Blue/provider collaboration, it is far from clear that competition is yet so intense and uninhibited in many health care markets that Blue/provider alliances are no longer effective or worth worrying about. Although the coming of competition has generated a great deal of discussion and consternation, its effects are still hard to detect in anything but anecdotes.[118] Most Blue Cross and Blue Shield plans have not yet definitively changed sides in the contest between consumers and providers.

There are few signs that competition has yet made enough headway in North Carolina markets to force NCBCBS to enter the fray on the consumer's side. Most NCBCBS contracts still embody free choice of provider, cost reimbursement for hospitals, UCR fee limits for physician services, and limited cost sharing, indicating that the plan has yet to break significantly with its tradition of catering to providers' essential interests. Although NCBCBS has introduced such innovations as HMO and PPO arrangements of its own,[119] these mechanisms do not yet face enough competition from independent health plans to induce them to bargain with providers as adversaries rather than as allies.[120] Indeed,

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[116]*See, e.g.*, Greenberg, *supra* note 100.

[117]*See supra* note 111; *infra* note 126. The precise inspiration for the Blue initiatives challenged in *Kartell*, 749 F.2d 922, and *Ball Memorial*, 784 F.2d 1325, is difficult to determine, but it is probable that these were competition-inspired departures from the Blues' historic policy of cooperating with provider interests. *But see supra* notes 112 & 114. If so, they should be regarded as exceptions that prove the rule. Why, for example, did such cases not appear much earlier?

[118]*See supra* note 107.

[119]Blue Cross's Personal Care Plan of North Carolina, Inc. (PCP) is an HMO of the individual practice association variety. In addition, Blue Cross has transferred some standard HMO contracts to PCP. As of April 1986, PCP had 21,000 enrollees, and it subsequently added 73,784 state employees. N.C. DEP'T OF INSURANCE, HEALTH MAINTENANCE ORGANIZATIONS: STATUS IN NORTH CAROLINA (April 1986 & Supp. July 3, 1986). Although NCBCBS officials claim that such recent innovations as a preadmission certification program, PPO and HMO arrangements, the participating physician program, and a program to encourage ambulatory surgery are evidence of their willingness to challenge providers, the text gives reasons for disputing this claim.

[120]Enrollment in active alternative health plans in North Carolina totalled 134,791 in April 1986, with 78,913 state employees added subsequently, for a total of 213,704. *Id.* Of these subscribers, Blue Cross's PCP enrolled 94,784. Several of the remaining plans were sponsored by dominant physician interests. Thus, the only truly independent plans able and philosophically willing to purchase physician services on a competitive basis were Health America, Kaiser, and PruCare, which enrolled 43,116, 23,366, and 11,877 subscribers, respectively (out of a state population of 5.9 million). *Id.*

these mechanisms may serve primarily as "fighting ships," weapons that allow NCBCBS and their provider allies to repel or discipline independent plans that seek to enter the market and to force providers into unwanted competition.[121] If so, the alliance's newly forged strategic capacity to slash prices to meet a competitive threat is more an impediment to than a manifestation of the emergence of effective competition in the state. Certainly NCBCBS's inability to control the price and cost of lithotripsy in North Carolina suggests that the old alliance is still very much intact.

B. Revising the Rules—"On Your Mark, Get Set, Go!"

If ESWL costs in North Carolina should rise in the aftermath of the repeal of CON requirements for lithotripters, the natural impulse will be to blame the legislature for deregulating this new technology. Nevertheless, because the true source of the problem lies in antiquated, pro-provider payment mechanisms, it can be argued that the legislature's greater failure was in deciding to deregulate only lithotripsy. Because payments for lithotripsy are only a very small percentage of insurers' overall payments for health care services, the threat of higher costs for this one service is unlikely to trigger the fundamental changes in financing arrangements that are needed if costs are to be brought under effective control by market forces. Across-the-board deregulation, however, would be such a dramatic change in the rules that all players on the demand side of the market, particularly NCBCBS and its customers, would have little choice but to reexamine their game plans. The sudden need of consumers and major purchasers of health insurance to find better allies in the cost-containment effort would bring about a competitive rush to find new defenses against provider overcharging, overspending, and overinvestment.

The main policy reason why most states are continuing CON regulation today, after the theoretical argument for it has been largely disproved,[122] is their belief that their local health care markets are not

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[121]A prepayment plan controlled by dominant provider interests presents the same hazard to competition that is presented by an informal Blue/provider alliance. On the antitrust and policy implications of prepayment plans controlled by dominant provider organizations, see FTC, *supra* note 101; Havighurst & Hackbarth, *Enforcing the Rules of Free Enterprise in an Imperfect Market: The Case of Individual Practice Associations*, in A NEW APPROACH TO THE ECONOMICS OF HEALTH CARE 377 (M. Olson ed. 198). For evidence of how a financing plan and a provider cartel, operating together, can exclude or discipline other payers, see Goldberg & Greenberg, *The Effect of Physician-Controlled Health Insurance:* United States v. Oregon State Medical Society, 2 J. HEALTH POL. POL'Y & L. 48 (1977). Because the same problems could also arise where the Blue/provider alliance was of the informal variety, Blue Cross's PCP may be more anticompetitive than procompetitive.

[122]The theory of CON regulation was that payment systems inevitably and inefficiently distort spending. *See* references cited *supra* note 12. Changes in purchasing practices can

yet sufficiently competitive to entrust them with the task of allocating resources and discouraging overinvestment.[123] Many states, however, are moving toward deregulation in small increments by raising the capital investment thresholds of CON requirements and exempting additional categories of providers and investments.[124] Although these steps may seem desirable in the general sense that they get government off providers' backs, deregulation is more likely to represent a pro-consumer change in the rules of the game if it is done on a wholesale rather than a piecemeal basis.[125] Only then would the legislature's move constitute a clear message to players who purchase and players who sell obsolete forms of health insurance that they can expect to be losers in future competition unless they change their strategies in fundamental ways. Only if that message is sent, received, and acted upon will consumers be in a position to hold their own in struggles over the uses of medical technology, old and new. A totally deregulated market is most likely to generate the radical rethinking and restructuring that is needed to force NCBCBS and other Blue Cross and Blue Shield plans finally to break with their provider allies and to use their bargaining power on the consumer's behalf.[126]

Because introducing meaningful change in health care financing mechanisms seems to be a slow and difficult process requiring the reeducation of many players and the devising of intricate new strategies, the best policy option available to North Carolina and other states is probably to announce the expiration of their CON laws as of some fixed future

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offset many of these distortions, however, and those that remain should be regarded as a cost of having insurance, not as inefficiency. *See supra* text accompanying notes 83-94; P. Joskow, *supra* note 12, at 21-31.

[123]An alternative justification for CON regulation of hospitals and their competitors is the alleged necessity to preserve cross-subsidization of indigent care, education, and research. Curbing competition enables hospitals to overcharge some patients and thereby to generate revenues to fund these worthy purposes. For arguments against using regulation for this purpose, see e.g., Havighurst, *The Debate Over Health Care Cost-Containment Regulation: The Issues and the Interests*, in Incentives Versus Controls in Health Policy 9 (J. Meyer ed. 1985). The case for controlling nursing home investments is unique to that industry, because of its heavy involvement with the Medicaid program, and is not considered here. *See* C. Havighurst, *supra* note 13, at 353-63.

[124]*See* Simpson, *supra* note 37.

[125]*See* discussion of a "market-forcing" regulatory strategy in C. Havighurst, *supra* note 13, at 321-44.

[126]There is a degree of irony in unleashing the market power of the Blue plans, which were created to serve providers and which served their interests so well for so long, against their original sponsors. *See Ball Memorial*, 784 F.2d 1325; *Kartell*, 749 F.2d 922, discussed *supra* notes 112 and 117. But there is a potential paradox as well. Where a Blue plan possesses market power, it might be vulnerable to attack under section 2 of the Sherman Act because of exclusionary practices of the type noted *supra* text accompanying notes 100-09. But to raise such a challenge, providers would have to claim that a Blue plan unlawfully monopolized the market by fostering the providers' own cartel.

date. The setting of such a sunset date should be done in a way that clearly warns purchasers and providers of health insurance of the need to find alternative means of cost containment, while providing them time to change their allegiances and to consider and install the defenses they prefer.[127] Such a legislative move, if accompanied by efforts to free the local market of legal and other restrictions on innovation, would materially improve the chances for a consumer victory not only in the lithotripsy game but also in the larger battle against wasteful health care spending.

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[127]The object would be to avoid problems similar to those allegedly encountered in Arizona and Utah when CON was repealed. *See supra* note 97. In particular, the federal government itself needs more time to change its current approach to reimbursing capital costs, which still invites excessive investment. *See supra* note 78.

Full Circle: The Return of Certificate of Need Regulation of Health Facilities to State Control*

James B. Simpson**

"Each certificate of need proceeding is an exercise in the inherently inexact science of determining how society's scarce health care resources might best be allocated."[1]

I. Introduction

Certificate of need (CON) programs are federally-funded, state-administered regulatory mechanisms providing for review and approval by health planning agencies of capital expenditures and service capacity expansion by hospitals and other health care facilities. Their primary purpose is to discourage unnecessary investment in health care facilities and to channel investment into socially desirable uses. At the beginning of 1986, forty-two states and the District of Columbia had statutes authorizing such programs, and four of the eight states without certificate of need statutes operated similar programs authorized under the Social Security Act.[2] A majority of states have administered such programs for over a decade.

State certificate of need programs generally operate in the following manner. A health care facility covered by the program must submit a permit application to an official state health planning agency before undertaking those capital expenditures and other projects subject to review. The average proposed expenditure is $1.7 million, and states review an average of 127 applications each year.[3] The state agency transfers the application for initial review to a local health planning organization, comprised of consumers and medical care providers in the

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[1]Kansas Dep't of Health & Env't v. Banks, 230 Kan. 169, 170-71, 630 P.2d 1131, 1133 (1981).

[2]State laws relating to health planning and certificate of need are frequently amended. Except as otherwise indicated, the information on state certificate of need programs presented in this article is current as of January 1, 1986.

[3]Office of Health Planning, U.S. Dep't of Health & Human Services, Status Report on State Certificate of Need Programs 9-10 (1985).

community to be served by the proposed project. Review criteria include consideration of community need, financial feasibility, expected quality of care, less costly alternatives, and accessibility of the project to underserved and indigent populations. The local organization conducts a public meeting at which interested persons may comment on the proposal. It then conveys its recommendation to approve or deny the project to the state health planning agency. The state agency conducts an administrative adjudicatory hearing on the application and renders a formal decision as to the need for the project. Administrative and judicial appeals may follow, and often do when multiple applicants compete to serve an identified community need. The ultimately successful applicant is awarded a "certificate of need" entitling it to proceed with its project.

A. Federal Involvement

Over the years, federal control over state health planning and certificates of need has waxed and waned. In the late 1960's, the federal government financed voluntary, non-regulatory health service planning programs at the local community and state levels. In 1972, Congress adopted section 1122 of the Social Security Act, providing for review, by states choosing to participate, of proposed capital expenditures by health care facilities reimbursed under Medicare and Medicaid.[4] Most states have participated in section 1122 at some time.[5] In 1975, Congress passed the National Health Planning and Resources Development Act of 1974[6] (NHPRDA or Act). The Act provided substantial funding for state and local health planning activities and effectively required states to adopt certificate of need laws conforming to federal standards.

After the passage of NHPRDA, states without certificate of need began to adopt statutes complying with the Act. States with pre-existing statutes took steps to comply with the federal requirements, which mandated a certificate of need program of extremely broad regulatory scope, subjecting a wide range of health care facilities and projects to a complex review and approval process. In a few years most states had programs resembling the federal model.[7]

With the advent of the Reagan administration in 1980, federal support for certificate of need fell on hard times. The administration entered office with an anti-regulatory platform and a strong interest in using

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[4]Social Security Amendments of 1972, § 221(a), 86 Stat. 1386 (codified as amended at 42 U.S.C. § 1320a-1 (1982 & Supp. I 1983)).

[5]*See infra* note 73 and accompanying text.

[6]Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified as amended at 42 U.S.C. §§ 300k-300n-6 (1982)).

[7]*See* Cohodes, *The State Experience with Capital Management and Capital Expenditure Review Programs*, in BUREAU OF HEALTH FACILITIES, U.S. DEP'T OF HEALTH & HUMAN SERVICES, HEALTH CAPITAL ISSUES 87-88 (DHHS Pub. No. (HRA) 81-14531 (1980)).

market incentives rather than regulatory controls to restrain the rising costs of health programs. It proposed to delete funding under NHPRDA, and although Congress did not fully concur, funding for health planning dropped sharply.[8] At the same time, however, the prescriptive terms under which the federal government awarded monies to states for certificate of need programs were greatly relaxed.[9]

Consequently, state certificate of need programs have begun to diverge from the federal model and from each other. Some states have entirely repealed their certificate of need laws.[10] Others have increased the scope and forcefulness of their regulatory controls.[11] The vast majority of states have modified their programs in recent years by streamlining the review process and narrowing the range of health care facilities and projects subject to review. In doing so, they appear to have shifted the goals of their certificate of need programs from systematic management of all institutional health care delivery to several more narrowly conceived purposes.

This Article describes changes in state certificate of need programs from their origins to the present. It concentrates on the types of health care facilities and categories of projects that have been subject to certificate of need review, because scope of coverage is the aspect of certificate of need that has changed the most over the years in response to changing state and federal regulatory policies.

A number of recent studies have considered procedural aspects of state certificate of need programs.[12] Several have attempted to evaluate the impact of such programs on health care expenditures.[13] Evaluations

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[8]In fiscal year 1982, annual NHPRDA funding was reduced by one half to $64.4 million. H.R. Rep. No. 218, 98th Cong., 1st Sess. 10 (1983). It has remained at that level ever since.

[9]*See infra* note 166 and accompanying text.

[10]*See infra* Table 1 and text accompanying note 192.

[11]*See infra* Table 2; noets 194-245 and accompanying text.

[12]Brown, *Common Sense Meets Implementation: Certificate of Need Regulation in the States*, 8 J. Health Pol. Pol'y & L. 480 (1983); Cohodes, *supra* note 7, at 68; Consedine, Jekel, & Dunaye, *Certificate of Need and the Pitfalls of Due Process*, 17 Inquiry 348 (1980); Nutt & Hurley, *Factors That Influence Capital Expenditure Review Decisions*, 18 Inquiry 151 (1981); *see, e.g.*, Colby & Begley, *The Effects of Implementation Problems on Certificate of Need Decisions in Illinois*, 3 Health Pol'y Educ. 303 (1983).

[13]*E.g.*, Ashby, *The Impact of Hospital Regulatory Programs on Per Capita Costs, Utilization, and Capital Investment*, 21 Inquiry 45 (1984); Howell, *Evaluating the Impact of Certificate of Need Regulation Using Measures of Ultimate Outcome: Some Cautions from Experience in Massachusetts*, 19 Health Services Reg. 587 (1984); Joskow, *The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital*, 11 Bell J. Econ. 421 (1980); Sloan, *Rate Regulation as a Strategy for Hospital Cost Control: Evidence for the Last Decade*, 61 Milbank Mem. Fund Q. 195 (1983); Sloan & Steinwald, *Effects of Regulation on Hospital Costs and Input Use*, 23 J. Law & Econ. 81 (1980). A survey and critique of other, unpublished studies may be found in Congressional Budget Office, Health Planning: Issues for Reauthorization 19-30, 57-64 (1982).

of the regulatory "toughness" of state certificate of need programs and variations in performance have also been undertaken.[14] However, there have been no recent reports examining in detail project coverage under certificate of need programs.[15]

II. Purposes of Certificate of Need

States undertake certificate of need programs to achieve various goals, which may differ from state to state and from one type of covered project to another. The major premise underlying certificate of need is that the market for institutional health services contains incentives to excess capital investment for which certificate of need programs are intended to compensate by limiting entry to facilities and services found to be medically necessary and affordable.[16] Every state certificate of need

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[14]*E.g.*, Policy Analysis, Inc. and Urban Systems Research & Engineering, Inc., Evaluation of the Effects of Certificate of Need Programs - A Report on Twelve State C/N Programs (1981) (Report prepared for Health Resources Administration, U.S. Dep't of Health & Human Services under Contract No. 231-77-0114); Begley, Schoeman & Traxler, *Factors That May Explain Interstate Differences in Certificate-of-Need Decisions*, 1982 Health Care Fin. Rev. 87.

[15]Surveys comparing certificate of need expenditure thresholds are distributed from time to time. *E.g.*, Division of Regulatory Activities, Office of Health Planning, U.S. Dep't of Health & Human Services, Status Report on State Certificate of Need Programs (1985), distributed in Office of Health Planning, U.S. Dep't of Health & Human Services, Program Information Letter 85-34 (1985) (expenditure thresholds as of July, 1984); Congressional Budget Office, Health Planning: Issues for Reauthorization (1982) (expenditure thresholds as of March, 1982). However, published reports identifying health care facilities and types of projects subject to certificate of need review date back several years. *See* Chayet & Sonnenreich, P.C., Certificate of Need: An Expanding Regulatory Concept 5 (1978) (survey of certificate of need and section 1122 coverage through approximately January, 1978); Cohodes, *supra* note 7 (survey of certificate of need coverage as of October, 1978); Curran, *A National Survey and Analysis of State Certificate-of-Need Laws for Health Facilities*, in Regulating Health Facilities Construction 88-89 (1974) (CON coverage as of the end of 1972 state legislative sessions); Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need,"* 59 Va. L. Rev. 1143 (1973) (CON coverage as of 1973).

[16]Proponents of certificate of need programs cite several reasons for market failure in institutional health care. *See, e.g.*, 42 U.S.C. § 300k-2 (1982) (market failure rationale for implementation of NHPRDA certificate of need function). First, such care is covered by private insurance or governmental benefit programs for most consumers, making them indifferent to the choice between treatments of differing costs and equal benefit, and in favor of all treatments with any marginal benefit, regardless of cost. Second, federal and state tax subsidies encourage individual consumers and employees, when bargaining collectively, to purchase more health insurance than they otherwise would, exacerbating the "moral hazard" of insurance coverage. Third, the prevailing methods by which insurers and government benefit programs pay for institutional health services discourage attention to costs and price competition by providers. Fourth, medical care delivery is organized in a manner that tends to allocate and expend resources without regard to cost. Hospitals, in particular, are organized so that a physician, acting as an insured patient's agent and

program implicitly incorporates this idea by providing for issuance of certificates on the basis of community "need." Some also contain express findings of market failure or of excess capacity in the health sector.[17]

The second major rationale for certificate of need is to protect public health by preserving and improving the quality of institutional health care. Many state certificate of need statutes include the preservation of quality of care as an express justification for their adoption.[18] In addition, quality of care considerations appear in many states' certificate of need review criteria as factors to be taken into account in approving or denying applications. For example, eight state certificate of need statutes expressly identify quality of care in existing facilities (either those of the applicant or other health care providers) as a review criterion.[19] Six certificate of need statutes explicitly require consideration of the expected

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lacking an independent incentive to limit volume or costliness of care, decides what services the patient receives. Fifth, there has traditionally been little competition among health insurance companies of the sort that would lead them to bargain with institutional health care providers over price and volume controls.

The foregoing characteristics cause institutional health care to exhibit excess demand for and consumption of medical technologies, high rates of introduction of new technologies and low rates of introduction of cost-reducing innovations, duplication of facilities and services with consequent unused capacity and failure to exploit economies of scale, and general organizational slack and inefficiency. Certificate of need programs are intended to prevent facility duplication and excessive rates of introduction of new technologies and services. They are not targeted at the underlying causes of market failure, nor are they designed to affect directly the demand for existing services or to improve efficiency and reduce operating costs in health care facilities. *See generally* P. JOSKOW, CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION 56-88 (1981).

[17]*E.g.*, COLO. REV. STAT. § 25-3-502 (1982); FLA. STAT. ANN. § 381.493(2) (Supp. 1985); ILL. ANN. STAT. ch. 111-1/2 ¶ 1152 (Smith-Hurd Supp. 1985); KY. REV. STAT. § 216B.010 (Supp. 1982); NEB. REV. STAT. § 71-5802 (Supp. 1984); N.H. REV. STAT. ANN. § 151-c:1 (Supp. 1983); N.C. GEN. STAT. § 131E-175 (Supp. 1983); OR. REV. STAT. § 442.025(2) (Supp. 1983); PA. CONS. STAT. ANN. § 448.102 (Purdon Supp. 1985); S.D. CODIFIED LAWS ANN. § 34-7A-22 (Supp. 1985); VT. STAT. ANN. tit. 18, § 2400 (1983); WASH. REV. CODE ANN. § 70-38-015 (Supp. 1986); W. VA. CODE §§ 16-2D-5(c), (d) (1985).

[18]*See, e.g.*, COLO. REV. STAT. § 25-3-502(4)(a) (1982); 1977 Hawaii Sess. Laws Ch. 178, § 1 (1977); KY. REV. STAT. § 216B.010 (Supp. 1982); MD. HEALTH-GENERAL CODE ANN. § 19-102(a) (Supp. 1985); NEB. REV. STAT. § 71-5802 (Supp. 1984); N.H. REV. STAT. ANN. § 151-c:1 (Supp. 1983); N.J. STAT. ANN. § 26:2H-1 (West Supp. 1985); N.Y. PUB. HEALTH LAW § 2800 (McKinney 1985); N.C. GEN. STAT. § 131E-175 (Supp. 1983); OR. REV. STAT. § 442.025(1) (Supp. 1983); 35 PA. CONS. STAT. ANN. § 448.102 (Purdon Supp. 1985); VT. STAT. ANN. tit. 18, § 2400 (1983).

[19]ALASKA STAT. § 18.07.041 (Supp. 1984); D.C. CODE ANN. § 32-304(a) (1981) (incorporating by reference 42 C.F.R. § 123.412(a)(18) (1985)); FLA. STAT. ANN. § 381.494(6)(c)(2) (Supp. 1985); MONT. CODE ANN. § 50-5-304(d) (1985), § 50-5-304(h) (1985) (incorporating by reference 42 C.F.R. § 123.412(a)(18) (1985)); S.D. CODIFIED LAWS ANN. § 34-7A-38(12) (Supp. 1984); WASH. REV. CODE ANN. § 70-38-115(2)(j) (Supp. 1985); W. VA. CODE § 16-2D-6(a)(22) (1985); WIS. STAT. ANN. § 150.39(10) (West Supp. 1985) (nursing homes).

quality of care in proposed facilities and services.[20] Most other states include quality of care considerations in their certificate of need regulations, often by incorporation of NHPRDA past quality standards.[21]

The quality protective function of certificate of need may be merged with its cost containment role. A number of epidemiological studies have demonstrated an association between volume of services provided in health facilities and reduced mortality rates, suggesting that as well as controlling costs, preventing excess, underutilized capacity improves quality of care.[22] The optimum service size standards found in certificate of need review criteria are based on these quality considerations.[23]

Third, certificate of need programs may be used to achieve a uniform geographic distribution of health services[24] or an equitable distribution

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[20]ARK. STAT. ANN. § 82-2311(d) (Supp. 1985); FLA. STAT. ANN. § 381.494(6)(c)(3) (Supp. 1985); GA. CODE ANN. § 31-6-42(a)(13) (1985); KY. REV. STAT. § 216B.040(2)(a)(2)(e) (Supp. 1982); ME. REV. STAT. ANN. tit. 22, § 309(1)(A) (Supp. 1985); R.I. GEN. LAWS § 23-15-4(d)(7) (1985).

[21]*See* 42 U.S.C. § 300n-1(c)(14) (1982); 42 C.F.R. § 123.412(a)(18) (1985).

[22]*See, e.g.*, Flood, Scott & Ewy, *Does Practice Make Perfect? Part I: The Relation Between Hospital Volume and Outcomes for Selected Diagnostic Categories*, 22 MED. CARE 98 (1984); Flood, Scott & Ewy, *Does Practice Make Perfect? Part II: The Relation Between Volume and Outcomes and Other Hospital Characteristics*, 22 MED. CARE 115 (1984); Luft, *The Relations Between Surgical Volume and Mortality: An Exploration of Causal Factors and Alternative Models*, 18 MED. CARE 940 (1980); Luft, Bunker & Enthoven, *Should Operations Be Regionalized: The Empirical Relation Between Surgical Volume and Mortality*, 301 NEW ENG. J. MED. 1364 (1970). It is postulated that increased volume is associated with diminished mortality rates because of a "learning curve" effect. Flood, Scott & Ewy, *supra*, at 123.

[23]*E.g.*, OR. ADMIN. R. 409-03-010(13)(b) (1985) (quality of care of proposed projects measured by sufficiency of expected volume to maintain staff skills); *see also* Humana, Inc. v. Department of Health & Rehabilitative Servs., 469 So. 2d 889 (Fla. Dist. Ct. App. 1985) (quality concerns justified criterion basing need for new facilities on full utilization of existing facilities); National Guidelines for Health Planning (a set of national "need" standards required to be considered by all state and local health planning agencies) regarding neonatal special care units, open heart surgery, cardiac catheterization, and radiation therapy, 42 C.F.R. §§ 121.204, .205, .207, .209 (1985). Each specifies a minimum volume of services identified by medical authorities as necessary to maintain quality of care.

[24]Standards for acceptable patient travel time to health facilities and acceptable risks of queuing at the facility are incorporated into states' criteria for identifying community need for new projects. *E.g.*, ALA. CODE § 22-21-264(4)(f) (1984) (certificate of need criterion of "evidence of the locational appropriateness of the proposed facility or service such as transportation accessibility . . ."); IOWA CODE ANN. § 135.64(1)(8) (West Supp. 1985); MONT. CODE ANN. § 50-5-304(1)(m) (1985) (CON criteria of distance, convenience, cost of transportation, and accessibility of health services for persons living outside urban areas); VA. CODE § 32.1-102.3(B)(6) (1985) (certificate of need criteria of topography and highway facilities in area proposed to be served); *see also* 42 C.F.R. § 121.201(b) (1985) (National Guidelines for Health Planning recommended 30 minute travel time to the nearest hospital for general acute care).

of health services among social and economic groups.[25] In such cases,

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[25]The foremost example is the use of certificate of need programs to encourage and protect health care facilities that internally subsidize socially desirable but unprofitable lines of business. For reasons of legal obligation or conscience, facilities may offer emergency or routine services to persons unable to pay, or accept Medicaid or other public program beneficiaries for whom reimbursement is less than cost or less generous than private payer reimbursement. Presumably, such facilities price other services or charge other payers above cost to recover their losses. When they do, it creates an opportunity for other facilities not so charitably inclined to undercut their prices and capture the paying market. Certificate of need programs can protect charitable subsidizers from cream skimmers by denying cream skimmers entry into the marketplace. *See, e.g.*, Collier Medical Center v. Department of Health and Rehabilitative Servs., 462 So. 2d 83 (Fla. Dist. Ct. App. 1985) (new hospital's certificate of need application denied to protect existing hospitals with high indigent patient loads from loss of paying patients, needed to subsidize indigent care, to new hospital). NHPRDA requires state programs to use several criteria designed to achieve this effect by expressing a preference for health care facilities that serve low-income and other "medically underserved" patients. 42 C.F.R. § 123.412(a)(6) (1985). *See also* 42 C.F.R. §§ 123.412(a)(5); 123.413 (1985). Numerous state certificate of need statutes also have medically-underserved access criteria. *E.g.*, CAL. HEALTH & SAFETY CODE §§ 437.11(b)(4)(c), 437.116 (Deering Supp. 1985) (certificate of need exemptions for facilities participating in Medicaid or providing certain volume of free care); D.C. CODE ANN. § 32-305(a)(2) (Supp. 1984) (certificate of need requirement that facilities provide a reasonable volume of uncompensated care); FLA. STAT. ANN. § 381.494(6)(c)(8) (Supp. 1985); GA. CODE ANN. § 31-6-42(a)(7), (c) (1985) (waiver of strict adherence to certificate of need criteria for minority administered hospital facilities serving socially and economically disadvantaged urban populations); MICH. COMP. LAWS ANN. § 333.22131(1)(j), (e) (Supp. 1985) (certificate of need criteria of access to residents and physicians, nondiscrimination in employment, patient admission or care, room assignment, training programs, and medical staff membership); NEB. REV. STAT. § 71-5853(1), (3) (Supp. 1985); 1985 N.H. Laws ch. 378, § 6 (to be codified at N.H. REV. STAT. ANN. § 51-C:7(III)) (certificate of need criterion of degree to which proposed facility is accessible to medically underserviced, including handicapped and indigent); N.C. GEN. STAT. § 131E-183(3), (3a), (13) (Supp. 1983); N.D. CENT. CODE § 23-17.2-05 (Supp. 1983) (incorporating by reference NHPRDA access review criteria); OKLA. STAT. ANN. tit. 63, § 2652.1(B)(3)(e), (6) (West 1984); PA. CONS. STAT. ANN. § 448.707(a)(9), (19) (Purdon Supp. 1985); VA. CODE § 32.1-102.3(B)(5) (1985); WASH. REV. CODE ANN. §§ 70.38.115(2)(e), (k) (Supp. 1986) (certificate of need criterion of hospital meeting or exceeding regional average level of charity care); W. VA. CODE § 16-2D-6(a)(4), (14), (18), (25) (1979); Executive Budget Bill, Act 29, 1985 Wis. Legis. Serv. 391 (West) (to be codified at WIS. STAT. § 150.69(13) (certificate of need requirement of acceptable plan for provision of health care to indigent); *see also* IDAHO ADMIN. CODE § 02.11400.01(a)(v) (1983) (Idaho section 1122 regulations); N.J. ADMIN. CODE tit. 8, § 33-2.1(a), (b) (1985) (prohibition on issuance of certificate of need to any facility that fails to provide or contractually commit itself to provide services to medically underserved populations residing or working in its service area as adjusted for indications of need). For court decisions upholding certificate of need decisions based on the performance in assuring access to medical care to the indigent or medically underserved, see *Collier*, 462 So. 2d 83 (Fla. Dist. Ct. App. 1985); Doctors Hosp. of Prince George's County v. Maryland Health Res. Plan Comm'n, 501 A.2d 1324 (Md. Spec. App. 1986) (hospital's record of lower Medicaid and indigent patient load than other area hospitals supported denial of its certificate of need application); Chambery v. Axelrod, 101 A.D.2d 610, 474 N.Y.S.2d 865 (1984) (certificate of need preference for facilities participating in

certificate of need regulation finds its justification not in market failure, but in compensation for undesirable consequences of market functioning.

Fourth, states may adopt certificate of need programs to limit public outlays for benefit programs, primarily Medicaid, or as adjuncts to state programs regulating health facility operating expenses.[26] For example, states have used certificate of need to control or to limit the supply of nursing home beds in order to limit Medicaid outlays for nursing home care.[27]

Fifth, certificate of need laws may be adopted to assure public participation in decision-making respecting major health facility projects and, by extension, in the overall configuration of institutional health care delivery. For example, the Maryland health planning statute provides that "The citizens of this State have a fundamental interest in planning the development of quality health services . . . ."[28] It establishes local health planning agencies and a consumer-dominated state health planning commission, and gives the local agencies and the general public roles in certificate of need review.[29] NHPRDA's provisions for local health planning agencies evince similar purposes.[30]

Medicaid upheld). The ultimate effect of employing certificate of need in this fashion is to tax indirectly the private paying patients of charitable health care facilities and to shield public budgets from the full costs of socially desirable services.

[26]*See* Mahler, *Barriers to Coordinating Health Services Regulatory Programs*, 6 J. HEALTH POL. POL'Y & L. 528 (1981).

[27]ME. REV. STAT. ANN. tit. 22, § 307(6-A) (Supp. 1985) (comparative review of new nursing home bed addition projects based on availability of legislative appropriations); MICH. COMP. LAWS ANN. § 333.22131(2)(f) (Supp. 1985) (certificate of need criterion, for nursing home bed addition, of consideration of Medicaid agency plans); MONT. CODE ANN. § 50-5-430(2) (1985) (authority to condition nursing home bed additions on availability of Medicaid funding); 1985 N.H. Laws Ch. 378, § 378:6 (to be codified at N.H. REV. STAT. ANN. § 151-C:5(II)(b)) (coverage of all health facility transfers of ownership except those subject to federal restrictions on asset revaluation for Medicare/Medicaid reimbursement purposes); PA. CONS. STAT. ANN. § 448.707(c)(7) (Purdon Supp. 1985) (nursing home bed addition criterion of consistency with Medicaid agency plans); VT. STAT. ANN. tit. 18, § 2406(a)(4) (Supp. 1985) (certificate of need criterion for nursing home bed addition of consideration of Medicaid agency plans); WIS. STAT. ANN. § 150.39 (West Supp. 1985) (nursing home project criteria of sufficient Medicaid funds appropriated to reimburse for care to be provided, and statutory ceiling on approveable nursing home beds to enable the state to accurately establish Medicaid budget); 1985 Wisc. Legis. Serv. Act 29, § 1975 (West) (to be codified at WIS. STAT. ANN. § 150.31). *See generally* Feder & Scanlan, *Regulating The Bed Supply in Nursing Homes*, 58 MILBANK MEM. FUND Q. 54 (1980).

[28]MD. HEALTH-GENERAL CODE ANN. § 19-102(a)(2) (Supp. 1985).

[29]*Id.* at (b)(5), 19-114, 19-118.

[30]42 U.S.C. §§ 300*l*-1,2, 300n-1 (1982) (establishment of consumer-dominated "health systems agencies" with formal role in certificate of need review); *see also* DEL. CODE ANN. tit. 16, § 9301 (1984); FLA. STAT. ANN. § 381.493(2) (Supp. 1985); 1975 Hawaii Sess. Laws ch. 178, Sec. 1; MICH. COMP. LAWS ANN. § 333.22131(1)(m) (Supp. 1985) (certificate of need criterion of non-profit health facility governance by body composed of a majority consumer membership broadly representative of the population served);

Until recently, another purpose for certificate of need in a few states was to avoid financial penalties threatened by the federal government if the state failed to adopt a certificate of need statute. From 1975 through 1982, NHPRDA required states to adopt certificate of need laws complying with its model provisions in order to receive funding under the Act and to avoid severe financial penalties.[31] Several certificate of need laws passed after 1975 cite NHPRDA compliance and avoidance of financial penalties as a reason for their adoption.[32]

III. Certificate of Need Before NHPRDA

A. Early Federal Support for Health Planning

Federal support for non-regulatory governmental planning of hospital and other health facility services began with the Hospital Survey and Construction Act of 1946, popularly known as the Hill-Burton Act.[33] During its three decades of operation, the Hill-Burton Act provided grants in participating states for construction and modernization of hospital and other health care facilities. A state Hill-Burton agency was required to prepare a medical facilities plan setting forth the number of facilities of various kinds in the state, the relative need for new facilities, and their appropriate distribution. In turn, construction grant applicants had to conform to the plan and were required to secure the approval of the Hill-Burton agency. When first enacted, Hill-Burton provided grants only to hospitals and public health centers.[34] The list of eligible facilities expanded over the years to include, at one time or another, nursing homes, rehabilitation facilities, chronic disease hospitals, diagnostic or treatment centers,[35] outpatient facilities, hospital-related

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Wash. Rev. Code Ann. § 70.38.015(1) (Supp. 1986) (state policy to encourage consumer and provider involvement in health planning);W. Va. Code § 16-2D-6(a)(26) (1985) (certificate of need criterion of existence of a mechanism for soliciting consumer input into the health care facilities decision-making process).

[31] *See infra* note 81 and accompanying text.

[32] 1975 Hawaii Sess. Laws ch. 178, Sec. 1 (purpose of certificate of need legislation is to conform to NHPRDA requirement); N.C. Gen. Stat. § 131E-175(5) (Supp. 1983) (legislative finding that failure to adopt certificate of need law would cause state to lose in excess of $55 million in federal funds); Tex. Rev. Civ. Stat. Ann. art. 4418h, § 1.01 (1976) (repealed 1985) (purpose of certificate of need statute is to meet requirements of NHPRDA). *Cf.* Colo. Rev. Stat. § 25-3-502(6) (1982) (legislative finding that certificate of need provisions differ from federal requirements, but advance state's own goals of quality assurance, access, and cost-effectiveness).

[33] Pub. L. No. 79-725, 60 Stat. 1040 (1946) (codified as amended at 42 U.S.C. § 291-2910-1 (1982)).

[34] Pub. L. No. 79-725 § 2, 60 Stat. 1040 (1946).

[35] Pub. L. No. 83-482, 68 Stat. 461 (1954).

extended care facilities and home health services, equipment acquisitions, and emergency rooms.[36] In later years, authority for grants to voluntary local health planning agencies to assist in the process of planning for community needs was incorporated into Hill-Burton.[37]

In 1966, Congress authorized new funding for state and local public or non-profit planning agencies to perform "comprehensive health planning," an activity with broader implications than disbursement of construction funds.[38] The state agencies identified public and private facilities, services, and personnel required both to meet the health needs of the state's population and to encourage cooperative efforts among health, education, welfare, and rehabilitation providers and agencies. Local agencies developed comprehensive regional or metropolitan plans for coordination of existing and projected services. In 1967, the comprehensive health planning laws were amended to require the state comprehensive health planning agency to assist health care facilities in developing individual programs for capital expenditures consistent with an overall state plan, and to provide for periodic state review of the facilities' capital expenditure programs.[39] The comprehensive health planning agencies were expected to provide consultation, not to control or regulate facility expenditures.[40] Nevertheless, the amendment clearly authorized, through the health planning process, official oversight of health facility expenditures and projects not financed with Hill-Burton or other federal funds. In this sense, this change was the progenitor of federal requirements for health planning regulation through certificate of need.

Regulations implementing the 1967 amendments listed the health care facilities whose capital expenditures were subject to review to include:

> All hospitals, sanitariums, nursing homes, and other facilities for the inpatient care of the sick, injured, or disabled, which are licensed or formally approved for such purposes by an officially designated state standards-setting authority, and all public or private non-profit clinics, health centers, and other facilities a major purpose of which is to provide diagnostic,

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[36]Pub. L. No. 91-296, 84 Stat. 336 (1970).

[37]Pub. L. No. 88-443, § 2, 78 Stat. 447 (1964).

[38]Comprehensive Health Planning and Public Health Services Amendments of 1966, Pub. L. No. 89-749, 80 Stat. 1180 (codified as amended at 42 U.S.C. § 246 (1982)).

[39]Partnership for Health Amendments of 1967, Pub. L. No. 90-174, 81 Stat. 533.

[40]*See* S. REP. No. 724, 90th Cong., 1st Sess., *reprinted in* 1967 U.S. CODE CONG. & ADMIN. NEWS 2076, 2078 ("This new requirement is intended to provide for assistance in the planning activities of health-care facilities, but is not intended to serve as a vehicle for control of the capital expenditure plans of any institution. The paragraph is designed to aid health care facilities in providing for more orderly planning so as to aid them in eliminating duplications and overlaps between the services they provide and the services provided by other facilities serving the same general area.").

> preventive, or therapeutic outpatient health care by or under the supervision of doctors of medicine, osteopathy, or dentistry; provided, that such term shall not include facilities operated by religious groups relying solely on spiritual means through prayer and healing and in which health care by or under the supervision of doctors of medicine, osteopathy, and dentistry is not provided.[41]

The regulations also provided that the expenditures subject to review would include all capital expenditures of any amount for "replacement, modernization, or expansion."[42]

These provisions drew virtually every type of institutional health care provider and expenditure within the purview of comprehensive health planning. Their inclusivity arose out of comprehensive health planning's origin in Hill-Burton planning (the scope of which naturally encompassed all the facilities and services Hill-Burton would fund) and out of a desire on the part of the federal government and the health planning community to oversee every aspect of health service delivery.[43] This viewpoint was, in turn, an outgrowth of the widely-held expectation among health policymakers at the time that prevailing economic and social forces would lead to centralized control of health services delivery in the United States along the lines of the national health services or universal health insurance systems of western European countries.[44] If such developments were inevitable, comprehensive health planning with very broad jurisdiction and built-in input from local communities seemed to be a logical prelude to their implementation in an American setting.[45]

Notably absent from these early federal ventures into health planning is any evidence of concern with distortions in the health care marketplace that might lead to excess capacity. The Hill-Burton program was intended to solve the opposite problem—insufficent private investment in health facilities. The comprehensive health planning legislation speaks of encouraging efficiency and economy through planning, but in the sense of rational resource management rather than of compensation for market defects.[46]

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[41] 42 C.F.R. § 51.4(i) (1969) (repealed 1976).

[42] *Id.*

[43] Applicable regulations defined the scope of comprehensive health planning to encompass the "health services, facilities and manpower to meet the physical, mental, and environmental health needs [of the populace] and the financial and organizational resources through which these needs may be met . . ." 42 C.F.R. § 51.4(c)(1) (1967) (repealed 1976).

[44] *See generally* THE REGIONALIZATION OF PERSONAL HEALTH SERVICES (E. Saward ed. 1976).

[45] *See* M. ROEMER, COMPARATIVE NATIONAL POLICIES ON HEALTH CARE 202 (1977).

[46] *See* Comprehensive Health Planning and Public Health Services Amendments of 1966, Pub. L. No. 89-749, § 2, 80 Stat. 1180 (legislative findings and declaration of purpose to promote health through public/private partnership planning for health services, manpower, and facilities).

However, a concern for preservation of quality of care and assurance of geographic and income-related access is evident in these programs.[47]

B. *Adoption of Certificate of Need Laws by the States*

While voluntary health planning agencies were appearing in the states and beginning to receive federal funding, several states had adopted certificate of need laws. The first was New York, which enacted its statute in 1966 after promoting regional voluntary planning since 1946.[48] Converting voluntary health planning into a regulatory mechanism appealed to other states.[49] In the next six years, twenty states adopted some kind of certificate of need program.[50] By the end of the 1973 legislative sessions, four more states had added certificate of need requirements and a total of twenty-three states had such programs.[51] Administrative responsibility for certificate of need programs was often

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[47]The Hill-Burton Act conditioned the receipt of grant funds on a health facility's agreement to provide a reasonable volume of uncompensated services and to make its facilities available to all persons residing in the area without discrimination on account of race, creed, or color. Pub. L. No. 79-725, § 2, 60 Stat. 1041 (1946). *See generally* Rose, *Federal Regulation of Services to the Poor Under the Hill-Burton Act: Realities and Pitfalls*, 70 NW. U.L. REV. 168 (1975); Wing, *The Community Service Obligation of Hill-Burton Health Facilities*, 23 B.C.L. REV. 577 (1982). The Act also mandated minimum maintenance and operation standards for funded projects, and prompted many states first to adopt health facility licensure programs. *See* A. SOMERS, HOSPITAL REGULATION: THE DILEMMA OF PUBLIC POLICY 118-32 (1969). The comprehensive health planning program combined these concerns in its announced goal of assuring "comprehensive health services of high quality for every person." *Id.*

[48]*Hearings on H.R. 6084 Before the Subcomm. on Health and Environment of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. 58 (1982) (testimony of James R. Tallon, Jr., Chairman, Committee on Health, New York State Assembly).

[49]Differing opinions as to the reason states adopted certificate of need laws have been offered. According to Curran, state legislators grafted CON programs onto voluntary health planning programs in response to public concern for rising hospital and health insurance costs. Curran, *supra* note 15, at 88-90. Havighurst suggests that certificate of need laws were adopted to strengthen voluntary health planning and, in some states, to limit proprietary hospital expansion. Havighurst, *supra* note 15, at 1148-50. Payton and Powsner attribute the passage of CON legislation to the efforts of the voluntary hospital establishment to forestall rate regulation and solidify its dominance of the hospital market. Payton & Powsner, *Regulation Through the Looking Glass: Hospitals, Blue Cross, and Certificate of Need*, 17 MICH. L. REV. 203 (1980). Certificate of need legislation was supported by the health planning establishment, the American Hospital Association, Blue Cross, state insurance commissioners, and various business and labor groups, and opposed by medical professional organizations, proprietary hospitals, and nursing home operators. Curran, *supra* note 15, at 90. The legislatures themselves appear to have been motivated by multiple concerns for cost containment, quality preservation, access assurance, and public participation in health facility decision-making. See *supra* notes 16-30 and accompanying text.

[50]Curran, *supra* note 15, at 85.

[51]Havighurst, *supra* note 15, at 1143-44.

assigned to comprehensive health planning agencies, which were often instrumental in securing passage of the certificate of need laws.[52]

Certificate of need programs adopted at this time varied considerably in their scope of coverage. They generally covered a narrower range of facilities and projects than were to be covered under subsequent federal regulatory health planning initiatives. A contemporary survey reported that nineteen programs subjected hospitals and nursing homes to regulation.[53] One state (Oklahoma) covered nursing homes, but not hospitals.[54] Three states (Michigan, Oregon, and Rhode Island) covered hospitals, but not nursing homes.[55] About half subjected freestanding outpatient facilities to review. None extended coverage to individual physician's offices.

Under project coverage, most states reviewed "capital expenditures" or similarly-labeled expansions of physical plants. Virtually all states had expenditure "thresholds," dollar amounts below which capital expenditures by health facilities were not subject to review. The expenditure thresholds varied widely from $25,000 to $350,000.[56] Over half of the states expressly covered increases in bed supply whether or not associated with a capital expenditure. All appeared to cover substantial expansion in services, sometimes without regard to expenditure thresholds. Acquisitions of medical equipment were expressly subjected to review in about half of the states, frequently with expenditure thresholds. However, several states exempted replacement of equipment. Finally, ten states covered both reductions in bed supply and/or termination of services.[57]

C. Section 1122

Congressional concern with the costs of institutional health services rose as the costs of the Medicare and Medicaid programs, established in 1965, increased. Among the reasons for increasing Medicare and Medicaid costs was the programs' open-ended payment to providers on the basis of costs incurred in the provision of services to beneficiaries.[58] In addition to paying for reasonable costs directly associated with patient care, Medicare and Medicaid paid for "capital costs," i.e., actual costs of interest on capital indebtedness, an allowance for depreciation on capital assets, and a fixed rate of return on equity capital used by

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[52]H.R. REP. No. 231, 92d Cong., 2d Sess., *reprinted in* 1972 U.S. CODE CONG. & ADMIN. NEWS 4989, 5065-66.

[53]Havighurst, *supra* note 15, at 1144.

[54]*Id.* at 1145.

[55]*Id.* at 1146 n.10.

[56]*Id.* at 1146 n.9.

[57]*Id.* at 1145-47.

[58]*See* Kinney & Lefkowitz, *Capital Cost Reimbursement to Community Hospitals Under Federal Health Insurance Programs*, 7 J. HEALTH POL. POL'Y & L. 648 (1982).

proprietary health facilities for patient care.[59] The Social Security Amendments of 1972 contained several measures designed to restrain Medicare and Medicaid program cost increases caused by incurred-cost reimbursement. They included mandatory utilization review, ceilings on payment for routine hospital inpatient costs, and the so-called "section 1122" program.[60] Section 1122 authorized the Secretary of Health, Education and Welfare to contract with individual states for a review and recommendation to the Secretary on the community need for capital expenditures proposed by or on behalf of health care facilities or health maintenance organizations.[61] State recommendations were to be based on state health plans, including those adopted by comprehensive health planning and Hill-Burton agencies. A negative state recommendation usually would lead to withholding by the Secretary of payment under Medicare and Medicaid for capital costs associated with the project.[62] Although section 1122's enforcement sanction—denial of federal program reimbursement—differed from that of state certificate of need programs, its purpose was similarly to deter unnecessary capital investment by health facilities. An additional purpose was to assure that Medicare and Medicaid reimbursement supported state health planning programs.[63]

1. Section 1122 Coverage.—Despite its origin in congressional concern over distorted incentives in Medicare and Medicaid reimbursement, as implemented by the Department of Health Education and Welfare, the section 1122 program extended the federal government's practice, begun under the comprehensive health planning program, of imposing extensive review requirements on virtually all categories of health facilities. Health care facilities subject to review under the Department's regulations encompassed the following: hospitals, psychiatric hospitals, and tuberculosis hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, providers of outpatient physical therapy services (including speech pathology services), kidney disease treatment centers (including freestanding hemodialysis units), and organized ambulatory care facilities such as health centers, family planning clinics, and surgicenters, which are not part of a hospital but are organized and operated to provide medical care to outpatients.[64]

In addition to health care facilities, health maintenance organizations were subject to review.[65] Projects were subject to review when undertaken

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[59] *Id.*

[60] Social Security Amendments of 1972, Pub. L. No. 92-603, § 221, 86 Stat. 1329 (codified as amended at 42 U.S.C. § 1320a-1 (Supp. I 1983)).

[61] *See generally* 42 C.F.R. §§ 100.101-100.109 (1985).

[62] 42 U.S.C. § 1320a-1(d) (1982).

[63] 42 U.S.C. § 1320a-1(a) (1982).

[64] 42 C.F.R. § 100.103(a)(1) (1974).

[65] 42 C.F.R. § 100.103 (1974).

by or on behalf of health care facilities or health maintenance organizations and when they involved capital expenditures that: (1) exceeded $100,000; (2) changed the bed capacity of the facility with respect to which such expenditures were made; or (3) substantially changed the services of the facility with respect to which such expenditures were made.[66] Capital expenditures that changed bed capacity and substantially changed services were defined by the Department of Health, Education, and Welfare in the following manner:

> [A] Capital expenditure that "changes the bed capacity" of a facility means a capital expenditure that results in any increase or decrease in licensed capacity under applicable state or local law, or, if there is no such law, the number of beds in a given facility as of January 1, 1973, as determined by the designated planning agency.
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> [B] Capital expenditure that "substantially changes the services" of a facility means a capital expenditure that results in the addition of a clinically related (i.e., diagnostic, curative, or rehabilitative) service not previously provided in the facility or the termination of such a service that had previously been provided in the facility.[67]

The extreme breadth of section 1122 coverage may have been justified from a comprehensive health planning perspective, but the connection between section 1122's broad coverage and the cost containment concerns that led to the program's adoption was difficult to identify.[68] The list of health care facilities covered under section 1122 seems to have been taken from the list of institutional providers eligible to participate in Medicare or Medicaid.[69] However, excessive capital investment of acquisition of costly new technology had never been associated with several of these providers, including home health agencies, outpatient physical therapy providers, or ambulatory care facilities. In fact, such providers were eligible for Medicare reimbursement in part because they offered less capital-intensive, lower-cost substitutes for hospital or nursing facility care.[70] It

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[66]42 U.S.C. § 1320a-1 (Supp. II 1972).

[67]42 C.F.R. §§ 100.103(a)(2)(iii),(iv) (1974).

[68]Reflecting the linkage of the two programs, the original section 1122 regulations also amended the comprehensive health planning regulations to conform their definitions of covered health care facilities. 38 Fed. Reg. 31,281 (1973) (amending 42 C.F.R. § 51.4(i)(4) (repealed 1976)).

[69]The list duplicated the list of Medicare-eligible providers in large part, and repeated the facility definitions in Medicare or Medicaid regulations.

[70]The Department of Health and Human Services eventually revised its interpretation of the purposes of section 1122 with regard to service and bed terminations. In 1983, it

would have been more consistent with Medicare and Medicaid cost control concerns to have exempted these facilities from section 1122 in order to channel investment toward them and away from institutional providers. Similarly, health maintenance organizations were a then-unusual form of organized health care delivery favored by the federal government because they appeared to operate with internal incentives for cost containment and reduced investment. They would also have been likely candidates for exemption from section 1122 coverage.

The Department's interpretation of the statutory phrases "substantial change in services" and "change in bed capacity" to include decreases as well as increases in bed capacity and to include terminations of services as well as service additions seems clearly inconsistent with the role of the section 1122 program to compensate for distorted Medicare incentives to excess capacity. The purpose for covering terminations of beds and services is presumably to maintain existing services, not to reduce capacity. Like the decision to cover a very broad array of non-institutional facilities, the Department's decision to cover terminations probably arose out of the perception that section 1122 was comprehensive health planning's successor, with the same broad purposes.[71]

D. Pre-NHPRDA State Participation in Capital Expenditure Review

State participation in the section 1122 program was optional.[72] By the beginning of 1975, thirty-nine states and two territories, many of which already had certificate of need programs, had agreed to enter the program.[73] The states' willingness to do so may have been due in part to the fact that section 1122 regulations and policy guidelines offered a means by which a state could participate in section 1122, but waive review of some of the exceedingly broad range of health care facilities and projects covered by section 1122. A state was permitted to "elect

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proposed to amend the section 1122 regulations to delete coverage of decreases in bed capacity and termination of services that are not associated with capital expenditures in excess of the current expenditure threshold. 48 Fed. Reg. 36,395 (to be codified at 42 C.F.R. §§ 3125.102(a),(b) (1983)). The preamble to the proposed regulations stated that such a deletion would be "consistent with Section 1122's central purpose of assuring that Medicare and Medicaid funds are not used to pay higher health care costs that result from duplication or irrational growth of health care facilities, while at the same time advancing the policy of the new Medicare prospective payment system, which provides health care facilities with incentives to eliminate inefficient services." *Id.* at 36,391.

[71] *Id.*

[72] 42 U.S.C. § 1320a-1(6)(1982).

[73] LEWIN & ASSOCS., INC., THE EXPERIENCE WITH THE SECTION 1122 CAPITAL EXPENDITURE REVIEW PROGRAM 14-15 (1985) (report prepared for Office of Health Planning and Evaluation, Office of the Assistant Secretary for Health, U.S. Dep't of Health & Human Services, under Contract No. 282-83-0072) distributed in OFFICE OF HEALTH PLANNING, U.S. DEP'T OF HEALTH & HUMAN SERVICES, PROGRAM INFORMATION LETTER 85-17 (1985).

not to review" categories or classes of projects identified in advance.[74] Although the extent to which states elected not to review in order to avoid the broad requirements of section 1122 prior to the passage of NHPRDA is not known, states' frequent election after NHPRDA suggests that states did resort to this provision to limit review scope.[75]

Twenty-six states had certificate of need programs, and seventeen states had both certificate of need and 1122 in early 1975.[76] By the end of 1975, every state except West Virginia and the District of Columbia had either a certificate of need or section 1122 program.[77] In short, well before the adoption of the NHPRDA, the vast majority of states had chosen to implement certificate of need or capital expenditure review. Their programs were generally more limited in scope than the broad programs favored by the federal government at the time. All these states later accepted NHPRDA funding, obliging themselves to conform to its requirements. However, for most states, the initial choice to adopt certificate of need or participate in section 1122 was independent of federal requirements.

IV. Certificate of Need Requirements of NHPRDA

Although regulatory health planning through certificates of need began in the states, it became fully established as national policy with the passage of NHPRDA. As originally adopted, NHPRDA embodied the ideal of comprehensive health planning: management of the health care delivery system by publicly-controlled, decentralized planning organizations. It was designed to induce every state to adopt a certificate of need law conforming to federal requirements; to give local planning agencies an official role in state planning and certificate of need review; and to enhance the regulatory toughness of state programs by improving the plans, criteria, and methodologies on which certificate of need decisions were based and providing for a more skilled professional staff for planning agencies.[78]

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[74]Bureau of Health Planning, U.S. Dep't of Health & Human Services, Election Not to Review Under the Section 1122 Program, Program Information Letter 82-04 (1981); Division of Comprehensive Health Planning, U.S. Dep't of Health, Education & Welfare, DPA Manual: Guidance and Procedures for Designated Planning Agencies in Administering Section 1122 of the Social Security Act 13 (1974). In August 1983, the Department proposed to codify this policy in amended section 1122 regulations. *See* 48 Fed.Reg. 36,396 (1983) (to be codified at 42 C.F.R. § 125.03).

[75]*E.g.*, Ga. Admin. Comp. § 272-3-.03 (1984); Iowa Admin. Code § 470-201.9 (1982) (election not to review under section 1122 all projects not required to be reviewed by certificate of need program).

[76]Chayet & Sonnenreich, P.C., *supra* note 15, at 5-6.

[77]*Id.*

[78]A good account of the adoption of NHPRDA is B. Lefkowitz, Health Planning: Lessons for the Future (1983).

NHPRDA's local health planning agencies, denominated Health Systems Agencies (HSA's), replaced voluntary local health planning boards. Elaborate requirements for public participation on HSA governing boards were established to assure that HSA's would be consumer-controlled and representative of all segments of the population.[79] HSA's had the task of providing community based health planning for specified geographical areas. Typically, there were three or four such health service areas, each served by an HSA, within each state. HSA's also were required to be allowed to participate in state certificate of need reviews by conducting a public meeting on proposed projects and submitting recommended findings with respect to projects.

NHPRDA provided for designation of state agencies, denominated State Health Planning and Development Agencies (SHPDA's), to develop a state health plan incorporating HSA plans and to administer certificate of need programs. A state advisory panel made up of HSA representatives was mandated. Certificate of need programs were required to provide for review of capital expenditures, substantial changes in services, and additions of beds by health care facilities. NHPRDA also prescribed detailed review procedure requirements and a laundry list of criteria for evaluating certificate of need applications. As the first of many attempts over the years to merge the two programs, a state participating in section 1122 was required to designate its SHPDA as the agency to perform section 1122 reviews.

NHPRDA did not literally compel states to adopt certificate of need programs consistent with its provisions.[80] Instead, it offered financial inducements to do so, in the form of federal funding for SHPDA's, and penalties for failure to do so. The penalties initially announced were severe. If a state did not have a certificate of need program in compliance with NHPRDA by a specified date, grants and contracts under numerous other federal health programs to state, local, and private entities in the state would be abruptly cancelled.[81] The funding at risk could amount to tens or even hundreds of millions of dollars in some states.[82] Because the funding at risk benefitted such diverse groups as community health

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[79]Pub. L. No. 93-641, § 3, 88 Stat. 2225, 2232-35 (1975) (current version at 42 U.S.C. § 300*l*-1 (1982)).

[80]North Carolina *ex rel.* Morrow v. Califano, 445 F. Supp. 532 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978).

[81]*See Health Planning and Resources Development Amendments of 1979: Hearings on H.R. 3041 and 3167 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. 108 (1979) (statement of Hale Champion, Undersecretary of HEW) (NHPRDA relies on "atomic bomb theory of penalty").

[82]Manor Healthcare Corp. v. Northwest Community Hosp., 129 Ill. App. 3d 291, 295, 472 N.E.2d 492, 494 (1984) (Illinois would lose $465 million over four years if not in compliance).

centers, medical students, academic health researchers funded by various national institutes of health, and medical, dental, and nursing schools, NHPRDA created a constituency strongly concerned with bringing state certificate of need programs into compliance. Although as a result of repeated congressional postponement of effective dates,[83] the compliance requirements of NHPRDA never became effective, the threat of their enforcement was sufficient to induce every state to make concerted, more or less successful, efforts to comply.

A. NHPRDA Coverage

NHPRDA's certificate of need coverage provisions were a revised version of those in section 1122, which were based on comprehensive health planning and Hill-Burton. Their source thus lay in the concept of systematic management of health care delivery, not in any theory of economic regulation. Although eventually scaled back, their broad scope and mandatory nature led states to adopt certificate of need programs with more extensive coverage than states would otherwise have chosen.

1. NHPRDA Coverage of Facilities.—Regulations adopted in 1977 to implement NHPRDA defined the health care facilities subject to certificate of need review to include: hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, intermediate care facilities, kidney disease treatment centers including freestanding hemodialysis units, and ambulatory surgical facilities. In addition, health maintenance organizations were subject to review.[84]

Although the source of this set of covered facilities was the prior section 1122 coverage provisions, there were several deletions from the pre-NHPRDA definitions.[85] First, providers of outpatient physical therapy were no longer required to be covered. Second, coverage of home health agencies was deleted.[86] The reason seems to have been a belief that market forces would adequately regulate the supply of these two types of facilities.[87] Third, coverage of organized ambulatory health care facilities was deleted. The reasons given were that "the variety of forms

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[83] *See infra* note 166 and accompanying text.

[84] 42 C.F.R. §§ 123.401, 404 (1977).

[85] The original NHPRDA regulations for certificate of need programs also amended the section 1122 regulations, making their health care facility coverage identical to NHPRDA's.

[86] Home health services were also excluded from the health services subject to review, in order to exclude from coverage both home health agencies and home health services offered in or through a health care facility or health maintenance organization. 42 C.F.R. § 123.404(a)(4) (1977).

[87] A later effort to reinstitute coverage of home health agencies was rejected in Congress in part on the grounds that "the supply of those services would not be excessive if they were not regulated and that market forces of supply and demand may appropriately allocate them." H.R. Rep. No. 190, 96th Cong., 1st Sess. 53, 76 (1979).

in which organized ambulatory health care facilities manifest themselves resulted in serious definitional difficulties under Section 1122" and that "in light of the uneven national distribution of organized ambulatory health care facilities in the states, the Secretary has decided against establishing a uniform national method for dealing with the problem at this time."[88] In fact, there was considerable debate in the Department of Health, Education and Welfare over the merits of ambulatory facility coverage, with attention focused on the costs associated with their acquisition of sophisticated medical equipment. A proposal was advanced to cover organized ambulatory health care facilities that generated annual revenues in excess of $1,000,000.[89] Although this proposal was not adopted, NHPRDA was later amended in response to these concerns to require certificate of need review of costly medical equipment used for inpatients but located in non-inpatient settings.[90]

Since 1977, the set of entities subject to certificate of need review under NHPRDA and section 1122 has remained substantially unchanged.[91] To its credit, the Department of Health and Human Services has resisted requests to reimpose coverage by regulation of home health agencies, physician offices, and various types of ambulatory care facilities originally covered under section 1122 or comprehensive health planning programs.[92]

2. Projects Subject to Review.—Over the years, the set of projects subject to review under NHPRDA has been amended frequently, usually but not invariably to reduce the range of projects subject to review. The Act originally required states to review "new institutional health services," as defined by the Secretary.[93] New institutional health services were defined by regulation as:

> 1. Construction, development, or establishment of a new health care facility or health maintenance organization;
> 2. Capital expenditures by or on behalf of a health care facility or health maintenance organization in excess of $150,000;
> 3. Increases in health care facility or HMO bed capacity, bed category changes, and bed relocations; and
> 4. New clinically-related health services offered in or through a health care facility or health maintenance organization.[94]

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[88]41 Fed. Reg. 11,691 (1976) (preamble to proposed regulations).

[89]Iglehart, *The Cost and Regulation of Technology: Future Policy Directions*, 55 MILBANK MEM. FUND Q. 25, 40-43 (1977).

[90]*See infra* notes 237-40 and accompanying text.

[91]*See* 42 C.F.R. § 123.401 (1985). Rehabilitation facilities were added to NHPRDA coverage in 1979 and have been proposed to be added to section 1122.

[92]*See, e.g.*, 50 Fed. Reg. 2009 (1985); 45 Fed. Reg. 69,755 (1980).

[93]42 U.S.C. § 300m-2(a)(4)(A) (1976).

[94]42 C.F.R. § 123.404 (1977).

3. New Construction and Acquisition Coverage.—Coverage of construction, development, etc., was a catch-all phrase for coverage of new hospital construction. It was probably included to clarify that new facilities as well as expansion of existing facilities were subject to review. Most pre-NHPRDA state certificate of need laws contained a similar term, and although it was deleted from the federal requirements in 1980,[95] most continue to do so.[96]

Capital expenditures for acquisitions of existing health care facilities or health maintenance organizations were exempt from mandatory review; states had the option of covering such transactions.[97] A rationale for this exemption was not announced. The Department had previously taken the position that section 1122 coverage of capital expenditures in excess of $100,000 by or on behalf of a health care facility included coverage of acquisitions of facilities, and it was not apparent why the same language would have a different meaning in the NHPRDA context.[98] The basis for the exemption was probably the absence of a strong justification for health planning agency review of transactions that did not necessarily involve changes in patient care services.[99]

4. Health Maintenance Organization Coverage.—As first adopted, much like section 1122, NHPRDA required coverage of new institutional health services offered by or on behalf of health maintenance organizations.[100] Both the health care delivery component of a health maintenance organization and its administrative and insuring aspects were apparently covered, as were physicians and other providers who contracted to serve HMO beneficiaries. An incidental effect of the coverage of health maintenance organizations themselves rather than health care facilities sponsored by HMO's was to require coverage of certain service-related projects offered by health maintenance organizations which were not required to be covered when offered by other health care facilities. For example, the establishment of a non-surgical ambulatory care facility component of a health maintenance organization was required to be covered regardless of cost, although establishment of such a facility by any other proponent would not have been subject to review unless associated with at least a $150,000 capital expenditure.

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[95]45 Fed. Reg. 69,746 (1980) (amending 42 C.F.R. § 123.404 (1977)).

[96]*See* Table 3.

[97]*See* 42 Fed. Reg. 4008 (1977).

[98]*See* 41 Fed. Reg. 11,706 (1976) (proposing 42 C.F.R. § 100.103(c)).

[99]Subsequent NHPRDA amendments added a provision requiring coverage of acquisitions if the SHPDA found that the services or bed capacity of the facility being acquired would be changed in the process. Health Planning and Resources Development Amendments of 1979, Pub. L. No. 96-79, 117, 93 Stat. 592, 617-18 (codified at 42 U.S.C. § 300m-6(d) (1982)).

[100]42 U.S.C. § 300n(5) (1976).

From the time of their adoption, the HMO coverage requirements of NHPRDA and section 1122 were criticized as overbroad and a potential hindrance to the spread of HMO's.[101] Congress and the Department of Health and Human Services soon began to cut back the HMO coverage provisions. In 1978, all references to HMO's were deleted from section 1122.[102] In 1979, a broad HMO exemption from NHPRDA was adopted. It required state certificate of need programs to exempt HMO's and inpatient health care facilities controlled or leased for a period of years by an HMO if the HMO enrollment was at least 50,000, 75% of the facilities' patients would be enrollees, and the facility would be geographically accessible to the enrollees.[103] The 50,000 enrollee requirement was deleted in 1981.[104] A similar but even broader exemption for facilities used by HMO's was placed in section 1122 in 1983.[105]

5. Increase in Expenditure Threshold.—The $150,000 NHPRDA capital expenditure threshold represented an increase over the $100,000 level under the section 1122 program. This was the first of repeated NHPRDA and section 1122 expenditure threshold increases over the years. The rationales offered for this first, modest increase were essentially the same as those offered each time the thresholds have been increased —that few significant capital expenditures cost less than the new, elevated threshold, and that due to inflation, the increase retained coverage unaltered in constant dollars.[106] Though not articulated by the Department, an additional justification for this and subsequent threshold increases was to remove certificate of need programs' authority over projects not involving major expansion of clinical health services. Health facilities, particularly hospitals, routinely incur capital expenditures for physical plant maintenance and improvement of non-patient care areas and equipment. Health planning agencies tend to be drawn into reviewing these costs by thresholds at the $100,000 level. Yet the agencies possessed no particular expertise to oversee the decisions of health facilities on the timing and amount of such transactions, the relationship between such projects and the rationales for certificate of need regulation were attenuated, and the delay caused by even cursory review of such projects generated considerable objection from regulated facilities.[107]

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[101]*See* Havighurst, *Health Maintenance Organizations and the Health Planners*, 1978 UTAH L. REV. 123, 141.

[102]*See* Health Maintenance Organizations Amendments of 1978, Pub. L. No. 95-559, § 14(b)(1)-(3), 92 Stat. 2141.

[103]Health Planning and Resources Development Amendments of 1979, Pub. L. No. 96-79, Sec. 117(a), 93 Stat. 614 (codified at 42 U.S.C. § 300m-6(b)(1) (1982)).

[104]Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 949(c), 95 Stat. 578.

[105]Social Security Amendments of 1983, Pub. L. No. 98-21 § 607(c), 97 Stat. 172.

[106]42 Fed. Reg. 4008 (1977).

[107]*See, e.g.*, Brown, *supra* note 12, at 485-86.

6. Changes in Bed Capacity.—Regulation adopted after NHPRDA's passage defined bed capacity changes subject to review as

> [a] change in bed capacity of a health care facility or health maintenance organization which increases the total number of beds (or distributes beds among various categories or relocates such beds from one physical facility or site to another) by more than ten beds or more than ten percent (10%) of total bed capacity as defined by the state, whichever is less, over a two year period.[108]

Bed category changes and bed relocations had not been subject to review under the 1122 rules. However, the Department decided to subject such transactions to certificate of need coverage on the grounds that substantial conversions could affect the delivery and cost of health services.[109]

Like the capital expenditure threshold increase, the exemption for "insubstantial" changes, i.e., bed capacity and other changes of ten beds or less or ten percent of total bed capacity, whichever was less, over a two-year period, was intended to shift regulatory review away from relatively minor projects. The Department had considered several versions of this exemption. It initially proposed to cover any addition, relocation, or category change.[110] Then, an extremely generous insubstantial change exemption was announced in the adopted regulations. It exempted bed capacity changes of less than forty beds or twenty-five percent of total bed capacity, whichever was less, over a two-year period.[111] This was a potentially major exemption from certificate of need, particularly for bed category conversions.[112] In recognition of the size of this loophole, shortly thereafter the "forty beds or twenty-five percent" exemption was changed to the "ten beds or ten percent" provision.[113] The current federal regulations cover substantial bed capacity changes associated with any capital expenditure, leaving the definition of exempt insubstantial changes up to individual states.[114]

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[108]42 C.F.R. § 123.404(a)(3) (1977).

[109]42 Fed. Reg. 4008 (1977). Required coverage of bed category changes and bed relocations was deleted from the federal regulations in 1985 in order to allow states greater flexibility in operating their certificate of need programs. 42 C.F.R. § 123.404(a)(2) (1985). *See* 50 Fed.Reg. 2008 (1985).

[110]41 Fed. Reg. 11,702 (1976) (proposing to adopt 42 C.F.R. § 123.404(a)(3)).

[111]42 Fed. Reg. 4029 (1977) (adopting 42 C.F.R. § 123.404(a)(3)).

[112]A forty bed addition would usually generate a capital expenditure in excess of the threshold and therefore come under review notwithstanding the exemption. The same thing would probably be true for bed relocations. However, for bed conversions the provision would, for example, allow a 160-bed acute care hospital facility to convert into a 90-bed acute care facility with a 70-bed skilled nursing unit in two years and a day, assuming no capital expenditure in excess of $150,000.

[113]42 Fed. Reg. 18,607 (1977) (amending 42 C.F.R. § 122.404(a)(3)).

[114]42 C.F.R. § 123.404(a)(2) (1985).

7. Coverage of Changes in Health Services.—The initial NHPRDA regulations provided for coverage of

> [h]ealth services, except home health services, which are offered in or through a health care facility or health maintenance organization and which were not offered on a regular basis in or through such health care facility or health maintenance organization within the twelve-month period prior to the time such services would be offered.[115]

The Department of Health and Human Services has never specified the services that fall within the term "health services," except to indicate that the term refers to clinical services.[116] It has stated, somewhat unhelpfully, that "[a]ny service is covered if it is included in the scope of coverage developed by the state."[117] Additionally, it has never clarified whether increases in the volume, intensity, or type of clinical services provided in a department constitute a new service, or whether only a new department or cost center would be covered.[118]

8. Bed and Service Terminations.—Capital expenditures exceeding the threshold for termination or reduction of beds or health services were also exempted from capital expenditure coverage. This provision represented a departure from section 1122, under which capital expenditures of any amount for termination of services or reduction of beds are covered.[119] Although the Department amended the NHPRDA regulations in 1980 to require coverage of capital expenditures associated with bed and service terminations, it recently deleted the requirement once again, so that at present, states are not required to cover terminations.[120] The Department has also proposed to delete the section 1122 requirement that terminations be covered.[121]

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[115]42 Fed. Reg. 4029 (1977) (adopting 42 C.F.R. § 123.404(a)(4)).

[116]50 Fed. Reg. 2014 (1985) (amending 42 C.F.R. § 123.401).

[117]42 Fed. Reg. 4008 (1977). The Department has occasionally expressed its views on whether certain activities should be considered new services. The 1977 regulations excluded home health services from the "health services" definition. In 1979, the Department adopted regulations requiring coverage of radiological diagnostic health services provided by fixed or mobile computed tomography (CT) scanning equipment under state certificate of need programs. 42 C.F.R. § 123.404(a)(5) (1979) (amended 1981); *see also* 42 C.F.R. § 100.103(a)(2)(iv) (1985) (addition of CT scanning is a substantial change in services under section 1122).

[118]*See* Community Psychiatric Centers of Or., Inc. v. Grant, Civ. No. 79-782 (D. Or. July 8, 1980), *rev'd on other grounds*, 664 F.2d 1148 (9th Cir. 1981) (interpreting federal regulations to cover extensive changes in the level or volume of clinical services).

[119]42 C.F.R. §§ 100.103(a)(2)(iii), (iv) (1985).

[120]42 C.F.R. §§ 123.404(a)(2),(3) (1985).

[121]*See* 48 Fed. Reg. 36,395 (1983) (to be codified at 42 C.F.R. § 125.102).

B. State Certificate of Need Coverage After Passage of NHPRDA

Passage of NHPRDA prompted more states to adopt certificate of need laws so that by 1978, forty states and the District of Columbia had certificate of need programs.[122] All but one of these covered hospitals and nursing homes. Georgia was the exception, covering only nursing homes. Thirty-six states covered ambulatory surgical facilities, an increase from earlier surveys probably due to coverage of such facilities under NHPRDA and section 1122.[123] Twenty-four states covered home health agencies, even though such coverage was not required under either NHPRDA or section 1122.[124]

Virtually every state subjected capital expenditures to review, including physical plant construction and other major capital expenditures. Thresholds varied from state to state, though less than they had in 1973. All but a handful of states had $100,000 or $150,000 thresholds.[125] This consensus on expenditure thresholds was undoubtedly due to the state participation in 1122 or NHPRDA, which had $100,000 and $150,000 thresholds respectively.

All but two states expressly covered increases in bed supply.[126] This was a greater number than had covered such transactions in 1973, probably reflecting national concern with excess bed capacity and the coverage of such transactions under 1122 and NHPRDA. More than half of the states continued to cover even single bed additions, rather than using the insubstantial increase exception permitted by NHPRDA. However, two states had adopted the "forty beds or twenty-five percent" increase exemption proposed by HEW in 1977.[127] Half of the states covered bed supply reductions. All but three states covered additions of new health services. Eighteen states covered deletions of services in one form or another.[128]

C. Health Planning and Resources Development Amendments of 1979

In late 1979, there was dissatisfaction in Congress with implementation of NHPRDA.[129] The costs of health care had continued to increase at a steady pace. Congress believed that excess capacity, the target of NHPRDA, was one cause of the increase. However, a number of econ-

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[122]Cohodes, *supra* note 7, at 87-88.

[123]*Id.*

[124]*Id.*

[125]*Id.*

[126]*Id.*

[127]CHAYET & SONNENREICH, P.C., *supra* note 15, at 11.

[128]Cohodes, *supra* note 7, at 88.

[129]H.R. REP. No. 190, 96th Cong., 1st Sess. 47-101 (1979); S. REP. No. 96, 96th Cong., 1st Sess. 50-93, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS 1306, 1355-98.

ometric studies circulating at the time had concluded that certificate of need programs, as then constituted, did not have a significant impact on the rate of hospital capital investment.[130]

In addition, certificate of need programs were generating a significant amount of controversy and litigation. A series of well-publicized reversals suggested that the planning agencies wavered between rigidly applying numerical need formulae that ignored the statutory criteria or rulemaking requirements and issuing unpredictable, ad hoc rulings.[131] Legal commentators had suggested a variety of reforms in the review process.[132] There was great concern that certificate of need coverage of expenditures for costly medical equipment was being evaded. Finally, there was concern that the existing pattern of certificate of need coverage in the law and regulations placed a very heavy workload on planning agencies and dictated that nearly as much time be spent on projects with small cost implications as on major projects.

In response, Congress passed the Health Planning and Resources Development Amendments of 1979.[133] In spirit, if not in coverage scope, they narrowed the focus of federally-mandated certificate of need from general health system management to economic regulation.[134] Although cost containment was a dominant purpose of the amendments, they also added statutory provisions mandating as review criteria the accessibility of proposed services and the quality of care previously provided by a certificate of need applicant.[135] A number of important procedural changes were adopted, including provisions requiring comparative review of com-

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[130]*See* Cohodes, *supra* note 7, at 76-77 and studies cited therein.

[131]*See, e.g.*, North Miami Gen. Hosp., Inc. v. Office of Community Medical Facilities, 355 So. 2d 1272 (Fla. Dist. Ct. App. 1978) (inconsistent application of criterion); Huron Valley Hosp., Inc. v. Michigan State Health Facilities Comm'n, 110 Mich. App. 236, 312 N.W.2d 422 (1981) (undisclosed preference for existing facilities over new construction); Irvington Gen. Hosp. v. Department of Health, 149 N.J. Super. 461, 374 A.2d 49 (1977); Sturman v. Ingraham, 52 A.D.2d 882, 383 N.Y.S.2d 60 (1976) (exclusive reliance on bed need formula in disregard of statutory criteria).

[132]*See, e.g.*, Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83, 111-115; Schonbrum, *Making Certificate of Need Work*, 57 N.C.L. REV. 1259 (1979).

[133]Pub. L. No. 96-79, 93 Stat. 592 (1979).

[134]*See* 42 U.S.C. § 300k-2 (Supp. III 1979) (legislative finding that states should exercise the certificate of need function under NHPRDA to allocate the supply of health services for which, by reason primarily of reimbursement mechanism distortions, the market does not or will not do so).

[135]42 U.S.C. §§ 300m-1(c)(6)(E),(14) (1982). The legislative history of these provisions reveals strong support for planning agency use of certificate of need programs as vehicles for reducing economic barriers to medical care for Medicare and Medicaid beneficiaries and the medically indigent. S. REP. No. 96, 96th Cong., 1st Sess. 78, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS 1306, 1374-76 (SHPDA's and HSA's should use their full range of authority and influence to remedy access problems).

peting applications and administrative appellate review of SHPDA decisions on certificate of need applications.[136] Several provisions were added to strengthen certificate of need decision-making by improving state health plan development and making consistency with the state health plan the primary review criterion.[137] Finally, after the amendments, NHPRDA required states to cover capital expenditures exceeding $150,000, capital expenditures substantially changing the bed capacity of a health care facility or substantially changing the services of such facility, new institutional health services entailing annual operating costs in excess of an expenditure minimum of $75,000, and acquisitions of major medical equipment costing in excess of an expenditure minimum of $150,000.[138]

1. Capital Expenditure Coverage.—Coverage of general purpose capital expenditures exceeding the expenditure minimum remained essentially as it was prior to the 1979 amendment.[139] Coverage of bed capacity changes and service changes was modified. Previously any bed supply increase, decrease, category redistribution, or relocation exceeding the "ten beds or ten percent" exemption was subject to review. Now such transactions were covered only if a capital expenditure was incurred to accomplish them.[140] In practice, this change probably served to exempt only a few previously-covered bed supply decreases and category redistributions.

Similarly, where previously all health service additions were covered, now such transactions were covered only if associated with a capital expenditure (or, as noted *infra*, if the new service's annual operating costs exceeded the operating cost expenditure threshold).[141] Whether or not this change had any noticeable effect on a state's scope of coverage

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[136]42 U.S.C. §§ 300k-1(b)(12)(D),(13)(A)(iii) (1982).

[137]42 U.S.C. §§ 300m-3, 300m-6(a)(5) (1982).

[138]42 U.S.C. §§ 300m-6(a)(1), 300n(5) (1982).

[139]The 1979 amendments did authorize states, in their discretion, to begin annually adjusting their capital expenditure (and annual operating cost) thresholds upward according to an index of changes in construction costs. Both the capital expenditure and annual operating cost thresholds were eligible for adjustment. A state opting to make full use of the adjustment could have increased its thresholds over the statutory maximum by a total of 23 percent by 1985. Applied to the increased capital expenditure threshold authorized in 1981, the current maximum complying capital expenditure threshold would be $736,200. *See* 50 Fed. Reg. 14,027 (1985).

[140]*Compare* 42 C.F.R. § 123.404(a)(3) (1977) *with* 42 C.F.R. § 123.404(a)(2) (1981) (amended 1985).

[141]The 1979 amendments were also interpreted by the Department of Health and Human Services to provide for coverage of capital expenditures associated with the termination of a health service. 42 C.F.R. § 123.404(a)(3) (1981) (amended 1985). The Department's rationale for covering bed and service terminations was that such coverage would permit states to use certificate of need programs to promote accessibility of health services, especially to the indigent and medically underserved. *See* 45 Fed. Reg. 69,757-81 (1980).

depended greatly on the state's definition of "health service." A state that defined "services" to include some clinical procedures (e.g., open-heart surgery) as well as brick-and-mortar departments might find some formerly-covered projects escaping review, since some clinical services can be commenced without the need to incur capital costs.[142]

2. New Health Services Exceeding an Annual Operating Cost Minimum.—A new category of coverage was added by the 1979 amendments. Implementing regulations provided for coverage in the following terms:

> [t]he addition of a health service which is offered by or on behalf of a health care facility which was not offered by or on behalf of the facility within the twelve-month period before the month in which the service would be offered, and which entails annual operating costs of at least the expenditure minimum for annual operating costs.[143]

The expenditure minimum for annual operating cost was another expenditure threshold, set at $75,000.[144]

The purpose of introducing an annual operating cost threshold into certificate of need coverage of new services was to trim review back to those projects with the greatest cost implications. Annual operating cost thresholds for certificate of need review had been under discussion for some time prior to the 1979 amendments. In 1978, a NHPRDA amendment bill restricting certificate of need coverage to health services entailing annual operating costs of $50,000 or more and acquisitions of medical equipment costing $150,000 or more passed the Senate but was not acted on by the House.[145] During this period, a number of health policy analysts argued that the institutional health services sector was not as capital-intensive as previously assumed and that the overall cost-inflating impact of capital investment came more from the additional operating costs generated by projects than from the capital costs of such projects themselves.[146] It was also observed that although high capital cost projects

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[142]However, non-capital expenditure service additions might be covered as additions of services entailing annual operating costs in excess of the expenditure minimum for annual operating costs. *See infra* note 202 and accompanying text.

[143]42 C.F.R. § 123.404(a)(3)(ii) (1981).

[144]The expenditure minimum for annual operating costs could be adjusted for inflation like the capital expenditure threshold. If a state made full use of the adjustment and increased its annual operating cost threshold to the elevated level authorized by 1981 NHPRDA amendments, its current expenditure minimum for annual operating costs would be $306,750.

[145]S. 2410, 95th Cong., 2d Sess. (1978).

[146]*See, e.g.*, D. SCHNEIDER, THE RELATIONSHIP BETWEEN CAPITAL AND OPERATING COSTS IN HOSPITALS: IMPLICATIONS FOR REGULATORY CONTROL 8-12 (Rennsalaer Polytechnic Inst., Final Report 1981) (estimates that six percent of hospital costs were attributable to capital costs).

were usually associated with high operating costs, some projects and services (e.g., renal dialysis stations) required low initial investment, but generated high costs of operation.[147] This work suggested that it might be appropriate to substitute an annual operating cost threshold for the capital expenditure threshold (or to retain a high threshold only for non-service-related capital expenditures large enough to have a cost impact on their own).[148] The coverage provisions in the 1978 Senate bill seem to have adopted this approach. Unfortunately, the 1979 amendments did not. Although they introduced an annual operating cost threshold for new services, they retained coverage of any service addition associated with a capital expenditure in any amount. Continued coverage of service additions associated with any capital expenditure probably rendered the annual operating cost threshold relatively unimportant, because most service additions require some capital expenditure and consequently are covered regardless of operating cost.

3. Major Medical Equipment.—The 1979 amendments introduced another new element of coverage: acquisition by any person of major medical equipment costing in excess of $150,000. Equipment not owned by or located in a health care facility was excluded unless: (1) the state's SHPDA found, after notice from the person acquiring the equipment, that it would be used to provide services for inpatients of a hospital; or (2) prior to September 30, 1982, the state certificate of need program provided for coverage of such equipment.[149]

Coverage of major medical equipment was adopted to prevent what was seen as a major gap in coverage giving rise to widespread evasion of certificate of need laws. At about the same time as NHPRDA was adopted, several types of expensive high-technology medical devices appeared on the market. Chief among these was the computed tomography (CT) scanner, a diagnostic radiological machine which typically cost in excess of $300,000 to acquire, generated annual operating costs in excess of $250,000, and (though rapidly accepted by clinicians) was of unproven

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[147] *Id.*; *see also* ARTHUR D. LITTLE, INC., DEVELOPMENT OF AN EVALUATION METHODOLOGY FOR USE IN ASSESSING DATA AVAILABLE TO THE CERTIFICATE OF NEED (CON) AND HEALTH PLANNING PROGRAMS 53-95, 187-89, and studies cited at 20-22 (Final Report prepared for Office of the Ass't Sec'y for Health, U.S. Dep't of Health & Human Services, under Contract No. 233-79-4003 (1982)).

[148] Alternatively, a very low capital expenditure threshold and no annual spending cost threshold could be used, but this would result in coverage of some low operating cost, low capital cost projects. *See* Cohen & Cohodes, *Certificate of Need and Low Capital-Cost Technology*, 60 MILBANK MEM. FUND Q. 307, 314-15 (1982).

[149] 42 U.S.C. § 300m-6(e)(1) (1982). The 1980 regulations specified that major medical equipment could be used to provide services to inpatients on a temporary basis in the case of natural disaster, major accident, or equipment failure without undergoing review. 42 C.F.R. § 123.404(a)(4)(iii) (1981).

efficacy.[150] Reports surfaced that hospitals were evading certificate of need and section 1122 coverage of such devices by placing them in adjacent non-hospital buildings or vesting their ownership in persons or entities not subject to review, while using the equipment for inpatients.[151] In response, the Department of Health, Education and Welfare published NHPRDA and section 1122 regulations requiring coverage of CT scanning as a new service.[152] The Department and various others also supported NHPRDA amendments that would have covered large capital projects in non-institutional settings, including acquisitions of costly medical equipment.[153] However, physician groups strongly opposed such a provision on the ground that it would extend certificate of need review into physicians' offices, and argued that the states ought to be given the option of extending coverage to medical equipment outside the institutional setting.[154] The provision adopted in 1979 represented a compromise between these views.

4. Expedited Review and Low-Priority Project Exceptions.—Various groups testifying before Congress about the 1979 NHPRDA amendments or commenting on the 1980 implementing regulations suggested amendments and changes to streamline certificate of need review and exempt certain classes or categories of projects. The leading target for exemption was projects for remodeling and replacement of obsolete facilities and equipment.[155] Because excess capacity is one of the primary rationales for adopting certificate of need statutes, such an exemption appears self defeating. By denying an application for a certificate of need to replace an obsolete facility or equipment, SHPDA's can exercise a "*de facto*" decertification power over existing excess capacity in the industry.[156] The

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[150]AMERICAN HOSP. ASS'N, CT SCANNERS: A TECHNICAL REPORT 43, 51 (1977). *See generally* U.S. CONG., OFFICE OF TECHNOLOGY ASSESSMENT, POLICY IMPLICATIONS OF THE COMPUTED TOMOGRAPHY (CT) SCANNER (1978).

[151]*See Health Planning and Resources Development Amendments of 1979: Hearings on H.R. 3041 and 3167 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. 521 (1979) (testimony of Russell Johan, Exec. Dir., Southeastern Wis. Health Systems Agency) ($750,000 CT scanner reportedly installed by physician group in old hamburger stand).

[152]42 C.F.R. §§ 100.103(a)(2)(iv), 123.404(a)(5) (1979) (amended 1981).

[153]*Health Planning Amendments of 1978: Hearings on S. 2410 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 2d Sess. 128, 134 (1978) (statement of Hale Champion, Secretary of HEW).

[154]Health Planning Amendments of 1978, S. Rep. 845 (to accompany S. 2410), 95th Cong., 2d Sess. 188-89 (1978).

[155]Exemption or streamlined review was not a new idea. The California certificate of need program had for several years provided a broad exemption for projects to remodel or replace facilities or equipment in existence at the time the state's certificate of need program was adopted. CAL. HEALTH & SAFETY CODE § 437.13 (West 1976) (repealed 1984). In addition, the Department of Health, Education and Welfare had advised states in 1977 of the option of "expedited review" of projects. *See* 42 Fed. Reg. 4007, 4009 (1977).

[156]*See* Kopit, Krill & Bonnie, *Hospital Decertification: Legitimate Regulation or a Taking of Private Property?*, 1978 UTAH L. REV. 179.

effect of placing an exemption in a certificate of need law is to forgo the opportunity to close down existing excess capacity and to limit the program's impact to new and expanded services. However, hospital decertification, whether accomplished directly or indirectly through denial of remodeling and replacement project applications, usually encounters powerful political opposition.[157] In addition, generally lower costs of remodeling and replacement, as opposed to new services, and stable or increasing patient populations mean that such projects are seldom turned down on their merits by planning agencies.[158]

The 1979 NHPRDA amendments did not adopt a remodeling and replacement exemption, but they did take a step in that direction by authorizing a form of limited review of certain replacement and high priority projects. The statute and regulations provided that capital expenditures (1) to eliminate or prevent imminent safety hazards (as defined by federal, state, or local fire, building, or life safety codes and regulations); (2) to comply with state licensure standards; and (3) to comply with the accreditation standards necessary for Medicare or Medicaid reimbursement should be approved unless the state agency found that the facility or service for which the capital expenditure was proposed was unneeded or that the obligation of the capital expenditure for the project was inconsistent with the state health plan.[159]

D. Continued Implementation of NHPRDA

Adoption of state certificate of need statutes in response to NHPRDA continued steadily after the passage of the 1979 amendments. By 1980, forty-seven states and the District of Columbia had certificate of need programs. Only Louisiana, Idaho, and Indiana lacked certificate of need statutes, and all three had 1122 programs. By the end of 1980, Idaho and Indiana had adopted certificate of need laws.[160] Several states terminated their 1122 agreements after they adopted certificate of need laws.[161] This change was due in part to the perception that the presence of a certificate of need program rendered section 1122 superfluous.[162] Additionally, the Department of Health and Human Services did not provide any additional funding for the cost of administering both certificate of need and 1122 programs.[163]

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[157] *See, e.g.*, Carpenter & Paul-Shaheen, *Implementing Regulatory Reform: The Saga of Michigan's Debedding Experiment*, 9 J. HEALTH POL. POL'Y & L. 453 (1984).

[158] *See infra* note 174.

[159] 42 U.S.C. § 300m-6(c) (Supp. III 1979).

[160] AMERICAN HEALTH PLANNING ASS'N, SELECTED DATA ON STATE HEALTH PLANNING AND RELATED PROGRAMS (1982).

[161] CONGRESSIONAL BUDGET OFFICE, HEALTH PLANNING: ISSUES FOR REAUTHORIZATION 14-15 (1982).

[162] S. Rep. No. 96, 96th Cong., 1st Sess. 43, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS 1306, 1348.

[163] *See* 44 Fed. Reg. 44,345 (1979).

E. Recent NHPRDA Amendments

Since the 1979 amendments, NHPRDA has not undergone major revision. However, the relationship between NHPRDA's certificate of need requirements and state certificate of need programs has been drastically altered, and NHPRDA's coverage provisions themselves have been modified.

The provision of NHPRDA authorizing appropriations for funding HSA's and SHPDA's expired September 30, 1982.[164] From that time until the present, Congress has temporarily continued the program in annual appropriations bills.[165] Each year, Congress has appended a rider to the appropriations bills forbidding the Secretary of Health and Human Services from terminating or penalizing a state that fails to have a certificate of need program complying with NHPRDA during the fiscal year covered by the bill.[166] The effect of these provisions has been to release states from the risk of losing federal funds by amending their certificate of need statutes to deviate from NHPRDA.[167] In the wake of these provisions, numerous states have adopted certificate of need coverage provisions differing sharply from NHPRDA.

The NHPRDA coverage provisions themselves also have been substantially cut back. The Health Programs Extension Act of 1980 added a permissive exemption from certificate of need coverage for projects "solely for research."[168] The NHPRDA exemption applies to projects solely for research that would not affect patient charges or substantially change bed capacity or medical and other patient care services of the facility (either initially or after the project has been developed).[169]

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[164]42 U.S.C. § 300n-6 (1982).

[165]Departments of Labor, Health and Human Services and Education and Related Agencies Appropriations Act, 1986, Pub. L. No. 99-178, Title II, 99 Stat. 1102, 1109 (1985); Continuing Appropriations 1985, Pub. L. No. 98-473, § 315(k), 98 Stat. 1837, 1963 (1984); Continuing Resolution 1984, Pub. L. No. 98-151, § 101(c), 97 Stat. 964, 972 (1983); Continuing Appropriations 1984, Pub. L. No. 98-107, § 101(f), 97 Stat. 733, 736 (1983); Further Continuing Appropriations 1983, Pub. L. No. 97-377, § 101(e)(2), 96 Stat. 1830, 1905-6 (1982); Continuing Appropriations Fiscal Year 1983, Pub. L. No. 97-276, § 133, 96 Stat. 1186, 1197 (1982).

[166]*E.g.*, Further Continuing Appropriations for the Fiscal Year 1986, § 124, 99 Stat. 1185, 1320 (1985) ("no penalty shall be applied nor any State or agency agreement terminated pursuant to sections 1512, 1515, or 1521 of the Public Health Service Act during fiscal year 1986.")

[167]A court has also held that the appropriations bills' riders implicitly repeal NHPRDA certificate of need requirements, rendering them unenforceable by third parties (who are not specifically barred from enforcement actions by the express terms of the riders). Harrisburg Hosp. v. Thornburgh, 616 F. Supp. 699 (M.D. Pa. 1985), *aff'd mem.*, 791 F.2d 918 (3d Cir. 1986).

[168]Pub. L. No. 96-538, § 307, 94 Stat. 3183, 3191 (1980) (codified at 42 U.S.C. § 300m-6(h) (1982)).

[169]42 U.S.C. § 300m-6(h)(1982). Proposals to grant special treatment for research and education projects had a long history. *See* 38 Fed. Reg. 31,380 (1973) in which the

In the Omnibus Budget Reconciliation Act of 1981, the NHPRDA capital expenditure threshold was increased to $600,000, the expenditure minimum for major medical equipment was increased to $400,000, and the expenditure minimum for annual operating costs was raised to $250,000.[170] The purpose of these changes was to "promote focusing the resources available for certificate of need reviews on the most expensive and future cost-generating new investments in medical care."[171]

High inflation during this period clearly necessitated some threshold increases simply to retain coverage at the originally adopted level. A $150,000 capital expenditure for construction in 1977 would have cost in excess of $232,000 by 1982.[172] Furthermore, many state CON programs were experiencing great problems keeping up with their review workload.[173] Low thresholds meant agencies were bogged down in review of routine replacement expenditures and expenditures for projects, such as acquisition of computerized medical information systems, telephone systems, and parking structures, that were unrelated to patient care. Approval rates for such projects tended to be very high.[174]

In addition, there was increasing recognition at this time that selectively raising thresholds would focus certificate of need review on the most costly and controversial projects. One study indicated that by

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Secretary rejected a proposal to give special consideration to health-related teaching and research capital expenditures under the section 1122 program. In 1978, Massachusetts added a provision to its certificate of need statute exempting capital expenditures and substantial changes in services if they were essential to the conduct of research in basic bio-medical or health care delivery areas or essential to the training of health care personnel, and would not increase capacity or charges. MASS. GEN. LAWS ANN. ch. 111, § 25(c) (West 1978) (amended 1980, 1981). With the Massachusetts law as a prototype, in 1979 the Association of American Medical Colleges recommended an amendment to NHPRDA which would have exempted from CON review medical education and research projects with only minor health service impacts. *Health Planning Amendments of 1979: Hearing on S. 594 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Labor and Human Resources*, 96th Cong., 1st Sess. 464 (1979) (statement of John A.D. Cooper, President, Association of American Medical Colleges).

[170]Pub. L. No. 97-35, §§ 936(a)(1)-(3), 95 Stat. 572 (1981) (codified as amended at 42 U.S.C. § 300n(5),(6),(7) (1982)).

[171]Omnibus Budget Reconciliation Act of 1981, H.R. REP. No. 208, 97th Cong., 2d Sess. 823 (1981).

[172]*See* U.S. DEP'T OF COMMERCE, CONSTRUCTION REVIEW 754 (December 1982); U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES: 1981 754 (1981). The section 1122 threshold was even further out of adjustment than the NHPRDA thresholds. A $100,000 construction expenditure in 1973 would have cost $225,000 by 1982. *Id.*

[173]The volume of certificate of need applications had increased while agency funding had decreased. See *supra* note 8; OFFICE OF HEALTH PLANNING, U.S. DEP'T OF HEALTH & HUMAN SERVICES, STATUS REPORT ON STATE CERTIFICATE OF NEED PROGRAMS 3 (1985).

[174]For example, from 1973-82 the certificate of need application approval rates in Florida for equipment replacement and expansion/renovation (not involving new services) were 99.4 percent and 98.1 percent respectively, while the approval rate for all other projects was 81.4 percent. OFFICE OF HEALTH PLANNING, FLA. DEP'T OF HEALTH & REHABILITATIVE SERVICES, ANNUAL REPORT ON CERTIFICATE OF NEED ACTIVITY 42 (1984).

increasing the capital threshold in New York from $100,000 to $1,000,000 and setting a $250,000 annual operating threshold for new services, three quarters of the projects reviewed in 1979 would have been exempted. The remaining projects subject to review, however, would account for 77% of the capital cost and over 96% of the operating cost implications of all projects proposed under the lower thresholds.[175] Similarly, a Department of Health and Human Services study indicated that almost 60% of the certificate of need/section 1122 applications in the 1979-1980 study year were for expenditures below $500,000. These projects accounted for less than 10% of the proposed costs. Furthermore, approval rates were higher for lower cost projects.[176] Building on these studies, a number of recommendations for certificate of need coverage reform were put forth at this time.[177] A common theme was the need to redefine coverage terms so as to focus on high priority projects. One study advocated high capital expenditure thresholds and an annual operating cost threshold for new services.[178] However, it also recommended covering, without regard to operating or capital cost, those new services or items of equipment for which quality of care rationales for certificate of need coverage were strongest.[179] Others recommended covering specified services or technologies rather than using expenditure or cost thresholds.[180] The threshold increases adopted by Congress in the 1981 Budget Act did not exactly follow these proposals.[181] Because

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[175]D. SCHNEIDER, *supra* note 146.

[176]E. COLEMAN, VOLUME AND VALUE OF CON/1122 APPLICATIONS (Bureau of Health Planning, U.S. Dep't of Health & Human Services, Program Information Note 81-7 (1981)).

[177]*See, e.g.*, J. HOWELL, REGULATING HOSPITAL CAPITAL INVESTMENT: THE EXPERIENCE OF MASSACHUSETTS (Nat'l Center for Health Serv. Res., Research Summary Series (1981)); D. SCHNEIDER, *supra* note 146; Cohen & Cohodes, *supra* note 148.

[178]D. SCHNEIDER, *supra* note 146, at 11, 15-16.

[179]*Id.*

[180]Cohen & Cohodes, *supra* note 148; *see also* J. HOWELL, *supra* note 177, at 21.

[181]Threshold levels were negotiable items in the political debate over health planning in 1981, with opponents of the program seeking to reduce the number of projects subject to review as much as possible and proponents attempting to hold threshold increases to the level necessary to obtain continued political support for the program. Thus, in the spring of 1981, the Department of Health and Human Services drafted a legislative proposal to "phase-out" NHPRDA which would have increased the capital expenditure threshold to $500,000 and exempted non-clinical projects such as parking lots and heating systems. *Administration Phase-out Bill Amended Consumer Majority Rule*, WASH. REP. ON MEDICINE AND HEALTH (1981). Starting with that figure, the House version of the 1981 Budget Reconciliation Act would have set the capital expenditure threshold at $500,000 and doubled the existing medical equipment and annual operating cost thresholds (then set at $150,000 and $75,000) to $300,000 and $150,000 respectively. It would have also provided for modest reductions in federal health planning funding. Omnibus Budget Reconciliation Act of 1981, H.R. REP. No. 158, Vol. 2, 97th Cong., 1st Sess. 383 (1981). The Senate version of the Budget Act would have radically defunded NHPRDA. Omnibus Budget Reconcilia-

the thresholds were raised across the board, they did not operate to select out specific classes of projects. In addition, because the federal regulations continued to require coverage of service additions associated with *any* capital expenditure, the effect of the annual operating cost threshold increase was not as great as might appear.

F. Section 1122 Amendments and the Medicare Prospective Payment System

Section 1122 program coverage had remained essentially unchanged from 1972. By the end of 1982, only fifteen states still had section 1122 agreements.[182]

However, in late 1982, there was renewed interest in the 1122 program.[183] From a political standpoint, the section 1122 program had certain features attractive to proponents of federally-funded health planning. Because the law required the Department of Health and Human Services to enter into an 1122 agreement with any state able and willing to do so and provided for payment to states for the reasonable cost of running 1122 programs, it seemed to be less vulnerable than NHPRDA to a hostile administration bent on defunding health planning or a Congress unable to decide whether to reauthorize or terminate NHPRDA.

Additionally, because the consequence of a negative 1122 recommendation was at most a partial reimbursement denial, not the denial of a permit to implement a proposed project, section 1122 programs could legitimately be characterized as less "regulatory" than state certificate of need reviews. The Medicare reimbursement sanction operated as a financial disincentive to invest, and projects did sometimes proceed without section 1122 approval.[184] These features were thought to make 1122 more palatable to deregulation proponents.

Interest in the section 1122 program was also sparked by congressional consideration at this time of fundamental reforms in the Medicare program. As part of a major social security bail-out package, Congress adopted a prospective payment system for Medicare.[185] The prospective payment system reimburses most acute care hospitals participating in

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tion Act of 1981, S. REP. No. 139, 97th Cong., 1st Sess. 878-79 (1981). Conference negotiations resulted in restoration of some federal funds in return for increasing each of the thresholds proposed in the House version by $100,000, resulting in the current $600,000, $400,000, $250,000 configuration. Omnibus Budget Reconciliation Act of 1981, H.R. REP. 208, 97th Cong., 2d Sess. 231 (1981).

[182]LEWIN & ASSOCS., *supra* note 73, at 14.

[183]*See* American Health Planning Ass'n, *1122 May Rise Again*, IV TODAY IN HEALTH PLANNING, No. 8 (1982).

[184]LEWIN & ASSOCS., *supra* note 73, at 5.

[185]Social Security Amendments of 1983, Title VI, 97 Stat. 149-152 (codified at 42 U.S.C. § 1395ww (1983)).

Medicare for acute inpatient services on the basis of a fixed amount per patient admission or "case," based on average costs in a base year for comparable classes of hospitals, adjusted for each hospital's mix of high and low cost cases (represented by diagnostic clusters), and capped by a "budget neutrality" ceiling under which total system reimbursement to hospitals may not exceed the amount that would have been paid under earlier payment systems.[186] The prospective payment system was intended to alter the underlying financial incentives in Medicare, encouraging above-average cost hospitals to economize.

Congress was unable to decide how to incorporate capital costs into the per case payment formula.[187] Consequently, incurred cost reimbursement for acute inpatient hospital capital costs (as well as capital costs incurred by other institutional Medicare providers not covered by prospective payment) was retained. However, Congress also provided that if it were unable to devise a method for incorporating capital costs into the per case payments by October 1, 1986, Medicare would cease to pay for capital costs associated with new acute inpatient hospital capital expenditures in a state after that date unless the state had a section 1122 agreement, and under the agreement the state had recommended approval of the capital expenditure associated with the project.[188]

The effect of this provision is to make section 1122 participation effectively mandatory in all states on October 1, 1986, unless Congress enacts contrary legislation.[189] By this provision, Congress sought to assure

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[186] *Id. See generally* 1 Medicare & Medicaid Guide (CCH) ¶¶ 4200-4395 (prospective payment regulations updated to January, 1986).

[187] It considered using a simple percentage increase in the amount paid to each participating hospital for non-capital costs. There were several difficulties with this "capital add-on" approach. On the average, the proportion of individual hospital total costs that is attributable to the cost of capital plant and equipment (*i.e.*, interest, depreciation) is about seven percent. Anderson & Ginsberg, *Prospective Capital Payments to Hospitals*, 2 HEALTH AFF. 52 (1983). However, the actual proportion varies widely from one hospital to the next on the basis of factors unrelated to individual institutional efficiency or prudent business strategy, including regional location, hospital type and ownership, and age of capital plant. A "seven percent add-on" to the per-case payment rates would tend to penalize some high capital-cost facilities on the basis of these unrelated factors and over-reimburse some low-cost facilities. A more generous add-on would avoid the penalty problem, but increase over-reimbursement and raise total Medicare capital costs over current levels. Both alternatives violate the guiding principles of the prospective payment system: rational economic incentives to hospital efficiency and "budget neutrality." This dilemma prompted Congress' indecision. *Id.*

[188] 42 U.S.C. § 1395ww(g)(1) (1983).

[189] Technically, the provision does not require states to adopt section 1122 programs. However, the penalty that hospitals would suffer in states without section 1122 programs would be so great that it is unlikely any state would opt not to participate in 1122. Compare the NHPRDA penalty for noncompliance described *supra* in text accompanying note 81.

that some mechanism for control of capital investment by health care facilities, either in the form of a formula-derived payment added to or otherwise incorporated into the per case payment, or continued payment at cost subject to review and approval by a planning agency, would always be in place. Several proposals have been advanced for incorporating capital costs into the prospective payment system, both with and without mandated planning agency review.[190]

Finally, Congress also amended the section 1122 expenditure threshold from $100,000 to $600,000, bringing it into line with the NHPRDA threshold.[191]

V. Current State Certificate of Need and Section 1122 Programs

A. Level of Participation in Certificate of Need and Section 1122

Table 1 identifies the present level of state participation in certificate of need or section 1122 programs. Forty-two states and the District of Columbia have certificate of need laws. Seven states have repealed certificate of need statutes since 1983: Arizona, Idaho, Kansas, New Mexico, Minnesota, Texas, and Utah. The other state presently without certificate of need, Louisiana, has never adopted a statute.

Fifteen states presently conduct section 1122 programs. Four (Idaho, New Mexico, Minnesota, and Louisiana) do not have certificate of need statutes. Idaho entered into its current section 1122 agreement when it repealed its certificate of need law in 1983. New Mexico and Minnesota retained their programs when they allowed their certificate of need statutes to lapse.

Minnesota and Kansas adopted statutes imposing moratoria on new hospital construction, bed capacity increases, and bed relocations until July 1, 1987,[192] and June 30, 1986,[193] respectively, at the time their certificate of need laws expired. In effect, their moratoria reestablished capital expenditure regulation, with limited coverage but criteria requiring automatic denial.

Thus, with the exception of Arizona, Utah, and Texas, at the beginning of 1986, every state had some form of health facility capital expenditure regulation such as a certificate of need program, a section 1122 agreement, a moratorium on new hospital projects, or some combination thereof.

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[190] *See* Anderson & Ginsberg, *Medicare Payment and Hospital Capital: Future Policy Options*, 3 Health Aff. 35, 40-43 (1984).

[191] 42 U.S.C. § 1320a-1(g) (1983).

[192] 1984 Minn. Sess. Law Serv., ch. 654, § 57 (West).

[193] 1985 Kan. Sess. Laws 970.

B. Coverage of Health Care Facilities

Table 2 identifies the facilities subject to review in each state with a certificate of need or section 1122 program.[194] Hospitals, skilled nursing facilities, and intermediate care facilities are subject to review in every state when covered transactions are undertaken by them or on their behalf. This unanimity is probably due to the fact that the causes of health care market failure justifying certificate of need regulation—generous insurance coverage, reimbursement incentives to excess investment, organizational insulation from cost increases—are most prevalent for services provided in these settings.[195] In addition, these facilities all have been required to be covered by either NHPRDA or section 1122 for several years.

Somewhat surprisingly, almost all jurisdictions cover ambulatory surgical centers. There is accumulating evidence supporting the intuitively plausible idea that ambulatory surgery offers a less expensive substitute for less complicated inpatient surgery, and on that ground one might expect states to exclude it from certificate of need in order to encourage its spread.[196] However, the increase in ambulatory surgery facilities that

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[194]Appendix A contains definitions, notes, and state supplementary comments for Table 2, organized by state. When the notation "N" appears in Table 2, the state-by-state comments in Appendix A contain explanatory information.

[195]The reasons for hospital and nursing home coverage are probably somewhat different. The level of private insurance or governmental third party payment for hospital care is very high (86% of total expenditures for hospital care) while consumer out-of-pocket payment for nursing home care is high (44% of total expenditures for nursing home care). High levels of patient cost-sharing for nursing home services weaken the market-failure argument for certificate of need coverage. However, the share of expenditures for nursing home care not paid out-of-pocket is borne disproportionately by public benefit and insurance programs (a large contributor to which are state Medicaid programs), not private health insurance. Gibson, Waldo & Levit, *National Health Expenditures 1982*, 5 HEALTH CARE FIN. REV. 1, 7 (1983). Consequently, coverage of nursing facilities can probably be attributed to the use of certificate of need programs to limit the availability of such facilities to Medicaid beneficiaries for the purpose of constraining Medicaid costs and encouraging patients to seek less costly, non-institutional forms of care. Thus, it would be no coincidence that Arizona, whose Medicaid program (the Arizona Health Care Cost Containment System) is the only one not providing nursing home benefits, was the only state in recent memory that did not cover nursing facilities under its (recently repealed) certificate of need law. *See* ARIZ. REV. STAT. ANN. § 36-433 (Supp. 1975) (repealed 1985). Similarly indicative of the Medicaid budget control rationale for certificate of need, Indiana's statute covers only those skilled nursing and intermediate care facilities that participate in Medicaid, and North Carolina, Ohio, and Virginia have partial exemptions from certificate of need review for nursing beds in retirement communities that do not participate in Medicaid, presumably on the grounds that the high levels of out-of-pocket payment for non-Medicaid nursing homes mean a price-sensitive consuming public. IND. CODE ANN. § 16-1-3.3-1(a) (West Supp. 1985); 1985 N.C. Adv. Legis. Serv. ch. 445 (to be codified at N.C. GEN. STAT. § 131E-183(c)); 1985 Ohio Legis. Bull. file 23, § 1 (Anderson) (to be codified at OHIO REV. CODE ANN. § 3702.53 (I)); VA. CODE § 32.1-102.3:1 (1985).

[196]*See generally* W. VALENTINE & B. PALMER, AMBULATORY SURGERY SERVICES 15-17 (Alpha Center Monographs: Methodological Note No. 5) (Office of Health Planning, U.S. Dep't of Health & Human Services, 1984) and studies cited therein.

would result from an exemption might have the undesirable short-term effect of increasing excess inpatient surgical capacity and reducing opportunities for hospital internal subsidization of services such as free care surgery revenues.[197] The widespread coverage of ambulatory surgery centers probably reflects concerns about imperfections in the ambulatory surgery market, the impact of such centers on hospital utilization, quality issues, and simply the fact that both NHPRDA and 1122 mandate ambulatory surgery coverage.

Most states have essentially exempted health maintenance organizations (HMO's) and health care facilities controlled by health maintenance organizations from certificate of need by adopting the NHPRDA exemption provisions or similar language. A few have taken the principle behind the NHPRDA exemption a good deal further. For example, California exempts any health care facility project other than a skilled nursing bed addition if over twenty-five percent of the patients served by the project are covered by prepaid health care.[198] It thus exempts facilities not actually controlled by health maintenance organizations if they are subjected to the efficiency incentives of health maintenance organizations or other forms of prepayment.

Coverage of other facilities is much more varied. Twenty states cover medically oriented residential care facilities. The market failure rationale for their coverage is weak, because by definition such institutions provide only minimal medical care services. However, such institutions are often operated by government units or reimbursed almost entirely by Medicaid and social service agencies, and certificate of need review may be simply a vehicle for governmental planning and budgeting for the services these facilities provide.[199] A similar rationale probably supports the remarkably widespread (thirty-one states) coverage of home health agencies.

Fifteen states cover all organized ambulatory care facilities. Several others cover one or more specific types of ambulatory facility. Fifteen cover hospices. In each of these instances, states have consciously decided

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[197]Meritorious cream-skimmers like ambulatory surgery facilities create a perpetual dilemma for health planning agencies, exacerbated by contradictory certificate of need criteria for evaluating such proposals. *Cf.* Collier Med. Center, Inc. v. Department of Health & Rehabilitative Servs., 462 So. 2d 83, 85 (Fla. Dist. Ct. App. 1985) (upholding the denial of a certificate of need for new for-profit hospital construction on the skimmer-favoring ground that an existing outpatient facility provided a less costly alternative and the skimmer-opposing ground that an existing public hospital would incur a revenue loss from the proposed facility's diversion of paying patients).

[198]CAL. HEALTH & SAFETY CODE § 437.10(g) (Deering Supp. 1986). Oregon has recently adopted a potentially even broader provision. It exempts hospitals if sixty percent of their inpatient revenue is received from payers employing prospectively-determined forms of reimbursement. 1985 Or. Laws, ch. 747, § 35 (to be codified at OR. REV. STAT. § 442).

[199]Whether the certificate of need administrative adjudicatory process is an efficient means of doing so is questionable. A few states have amended their statutes recently to exempt government-run health care facilities. *See, e.g.*, MO. ANN. STAT. § 197.315(18) (Vernon Supp. 1985); MONT. CODE ANN. § 50-5-309(1)(b) (1985).

to cover health facilities that are not covered under NHPRDA and that the Department of Health and Human Services has expressly chosen not to cover.

The extent to which these institutions actually undergo certificate of need review depends considerably on the project coverage provisions of their state's certificate of need law. Most of the states that cover ambulatory facilities have sufficiently high capital expenditure and major medical equipment thresholds that the facilities' typically modest capital acquisitions in these areas would escape review. However, most of the states that cover ambulatory facilities would subject the initial establishment or construction of such facilities to review.

The reasons states cover ambulatory health care facilities are not immediately apparent. As with ambulatory surgery centers, coverage is probably justified by concern for impact on hospital use and cream-skimming or by concern for access and quality.[200]

1. Coverage of Capital and Other Projects.—The states have made major changes in project coverage. Going beyond recent NHPRDA amendments and essentially implementing the recommendations of policy analysts in the field, they have de-emphasized review of projects not directly related to patient care and have focused on large expenditures and additions of new technology and services. Table 3 identifies the capital expenditures and other projects subject to review under the states' certificate of need and section 1122 programs.[201]

Project coverage varies widely among the states. However, some of the variation may be more apparent than real. First, states may simply choose different words to cover essentially the same transactions.[202] For example, there is probably no difference in reviewability of bed capacity increases between a state that covers capital expenditures for bed capacity increases and a state that covers bed capacity increases without regard to expenditure, because a bed capacity increase almost invariably involves a capital expenditure (for the beds themselves if nothing else). Second, several states have redundant project coverage provisions. Covering both service additions associated with a capital expenditure and service additions regardless of capital or operating cost is an example. If these kinds of variations are set aside, it is apparent from Table 3 that most

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[200]Stated rationales for ambulatory care facility coverage are extremely difficult to find. *But see* STATEWIDE HEALTH COORDINATING COUNCIL, STATE OF MICHIGAN, 2 MICHIGAN STATE HEALTH PLAN 1983-1987, at 25-26, 28 (1983), which justifies coverage of outpatient facilities and public health centers on quality of care and geographical accessibility grounds.

[201]Appendix A contains definitions, notes, and state-by-state supplementary comments for Table 3, organized by state. When the notation "N" appears in Table 3, the state-by-state comments in Appendix A contain explanatory information.

[202]Some of this may be accounted for by the fact that states drafted their certificate of need statutes and regulations at differing times and attempted to comply with the version of federal certificate of need law and regulations then in effect.

states with certificate of need and/or section 1122 programs cover general-purpose capital expenditures incurred by or on behalf of health care facilities, bed-related changes of various types, additions of new health services, acquisitions of medical equipment, and construction, development, or establishment of new health care facilities. This is essentially the coverage pattern prescribed by NHPRDA in its current form.

The states with wholly distinct coverage provisions are few. Alaska and California do not have general-purpose capital expenditure thresholds; instead they cover specified transactions.[203] All states cover bed and service-related projects, and the states that do not expressly cover equipment acquisitions or new construction probably review such transactions under capital expenditure or service addition provisions.

2. General-Purpose Capital Expenditure Coverage.—As noted above, virtually every state covers capital expenditures undertaken by or on behalf of health care facilities. Coverage of general purpose capital expenditures has been a common feature of health planning agency review of health facility projects since the inception of comprehensive health planning.[204] However, the levels of state capital expenditure thresholds have increased significantly.[205] Many states have raised their thresholds above the maximum federal level (which would be $736,200 in states taking full advantage of the threshold inflator).[206] This practice appears most common in the western states, where Alaska and California have capital thresholds set at one million dollars for certain specified projects and general purpose thresholds in several other states are at similar levels.[207] Five other states have thresholds exceeding the federal level.[208] Colorado's two million dollar threshold is the highest in the country.

However, there have been proposals to raise thresholds still further. In the 97th Congress, the House of Representatives passed, but the

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[203]California has the most unusual coverage. New hospital construction, bed capacity increases, and additions of seven specified hospital services are the only hospital projects covered. By contrast, establishment of surgery clinics, any capital expenditure for expansion of surgical capacity, capital expenditures in excess of $1 million for medical or other equipment, services, or modernization by clinics and additions of services by clinics are covered. None of the rationales for ambulatory surgery coverage under certificate of need programs appear to justify more extensive coverage of ambulatory surgery than of hospitals. The California law also contains a bewildering array of special exemptions, and an extremely broad authorization for the SHPDA to issue certificates of need in disregard of the review criteria in individual cases. CAL. HEALTH & SAFETY CODE § 437.10,.11,.116,.118,.12,.15 (Deering Supp. 1985).

[204]*See supra* note 57 and accompanying text.

[205]*See* Table 3.

[206]*See supra* note 106.

[207]The general purpose threshold for Colorado is $2,000,000; for Montana, $750,000; for North Dakota, $750,000; for Oregon, $1,000,000 or $250,000 plus 0.5 percent of gross revenues; and for Washington, $1,071,000. *See infra* Table 3.

[208]Indiana ($750,000); Mississippi ($1,000,000); New Hampshire ($1,000,000); North Carolina ($1,000,000); and Tennessee ($1,000,000). *Id.*

Senate did not act on, a bill to supplant NHPRDA which would have increased the federal capital expenditure threshold to five million dollars.[209] In the 98th Congress, bills with capital thresholds ranging from one to five million dollars were introduced, and the Administration expressed its preference for the higher of these thresholds.[210] None of these bills passed.

In the states that have not chosen to exceed the NHPRDA threshold level, few have retained the expenditure thresholds they had in 1980. Only four states have kept capital expenditure thresholds at the $150,000 level.[211]

A state elevating its capital and other expenditure thresholds to levels at or above one million dollars greatly increases the temptation to health care facilities to attempt to evade certificate of need review by artificially dividing projects into two or more stages, each costing less than the threshold. When the expenditure threshold is $100,000, the risks of evasion of certificate of need by dividing, for example, a $198,000 project into two $99,000 stages are not likely to be worth the benefit to the facility. But with a five million dollar threshold, project division could permit a project costing nearly ten million dollars to escape planning agency scrutiny. In response to this problem, several states have adopted statutory prohibitions on project division undertaken for the purpose of avoiding certificate of need review.[212]

3. Non-Clinical Exemptions and Streamlined Review Provisions.— Even more often than they have elevated thresholds, the states have reduced project coverage by a variety of categorical exemptions and by expedited review provisions. First, a number of states have adopted exemptions for expenditures not related to clinical services. The state of Washington, for example, exempts capital expenditures that will not substantially affect patient charges and that are for communications and parking facilities; mechanical or electrical ventilation, heating, and air-conditioning systems; energy conservation systems; repairs to physical

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[209]H.R. 6173, 97th Cong., 2d Sess. § 5 (1982).

[210]*See* H.R. 2934, 98th Cong., 1st Sess. (1983); H.R. 2935, 98th Cong., 1st Sess. (1983); Letter from David Stockman, Director, Office of Management and Budget to Rep. Edward Madigan (Aug. 4, 1983).

[211]Delaware, Michigan, Rhode Island, and Vermont. Two states, Oklahoma and South Dakota, have raised their capital thresholds for hospitals to current NHPRDA levels while retaining lower thresholds for nursing facilities.

[212]D.C. CODE ANN. § 32-302(12)(B) (1981); KY. REV. STAT. § 216B.061(2) (Supp. 1982); ME. REV. STAT. ANN. tit. 22, § 315 (1980); MISS. CODE ANN. § 41-7-173(b)(ii) (Supp. 1984); NEB. REV. STAT. § 71-5832 (Supp. 1984); N.H. REV. STAT. ANN. § 151-C:4(I)(C),(II) (Supp. 1983); 1984 Ohio Legis. Bull. § 3702.59(B) (Anderson); OR. REV. STAT. § 442.320(d) (Supp. 1983); S.D. CODIFIED LAWS ANN. § 34-7A-33 (Supp. 1984); VT. STAT. ANN. §§ 2403(a)(3),(b) (1983); W. VA. CODE § 16-2D-2(i)(2)(B) (Supp. 1984); WIS. STAT. ANN. § 150.07 (West Supp. 1985).

plant necessary to maintain state licensure; acquisition of data processing and other equipment; construction of facilities not used for direct provision of health services; land acquisition; and refinancing existing debt.[213] In addition, a significant number of states provide for expedited or streamlined review of various categories of projects. Most states have adopted the NHPRDA-authorized provision for limited review of projects to eliminate safety hazards or to comply with licensure or accreditation requirements.[214] Numerous states also provide for expedited review of projects such as capital expenditures not involving service or bed capacity increases, service terminations, expenditures below a threshold somewhat higher than their statutory coverage minimum, and the like.[215] Some

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[213]WASH. REV. CODE ANN. § 70.38.105(4)(d) (Supp. 1986); *see also* ARIZ. REV. STAT. ANN. § 36-433(E)(6) (Supp. 1975-1984) (energy conservation projects); CAL. HEALTH & SAFETY CODE § 437.10(e)(5) (Deering Supp. 1985) (parking lots and structures, telephone systems, and non-clinical data-processing systems); COLO. REV. STAT. § 25-3-503(7) (1982) (residential units, parking, telephone systems, day-care, mailroom, gift shops, printshops, medical office buildings or clinics organized primarily for the delivery of physician services, morgue, heating and air conditioning, blood bank, dietary/cafeteria, laundry and linen, administration, medical records, business office, housekeeping, central supply, materials management, library, reception, code violations in non-clinical areas, ground transport services (not including air), land acquisition, research, education, non-diagnostic management information systems); CONN. GEN. STAT. ANN. § 19a-155 (West Spec. Supp. 1984) (energy conservation systems); GA. CODE ANN. §§ 31-6-47, 47(c) (1985) (waiver of review of projects including those defined by regulation GA. ADMIN. COMP. ch. 272-2, § 272-2-07 (1984), such as site acquisitions, transfers of previously-approved major medical equipment not resulting in institution of a new clinical health service at the transferee facility, and expenditures below the capital expenditure threshold for minor repair or replacement of equipment associated with the physical plant); HAWAII REV. STAT. § 323D-54(b) (Supp. 1984) (projects determined not to have a significant impact on the health care system, defined by regulation [HAW. ADMIN. CODE § 11-186-96 (1981)] to include acquisition of a capital asset by a means other than purchase; bed supply increases or decreases not exceeding the capital expenditure of annual operating cost threshold; addition or deletion of a service not exceeding an annual operating cost threshold; certain structural repairs; equipment replacement not exceeding twice the expenditure minimum; non-patient care projects such as parking lot structures not exceeding twice the expenditure minimum); MONT. CODE ANN. § 50-5-309(1)(a) (1985) (expenditures for non-medical and non-clinical facilities and services unrelated to the operation of the health care facility); OR. REV. STAT. § 442.320(b) (Supp. 1983) (statutory authorization for adoption of rules providing for waiver of review of expenditures for repairs by replacement of equipment, non-clinically related capital expenditures, and offering or development of a new health service of a non-substantive nature); Executive Budget Bill, Act 29, 1985 Wis. Legis. Serv. 390 (West) (to be codified at WIS. STAT. ANN. § 150.613 (West)) (hospital heating, air conditioning, ventilation, electrical systems, energy conservation, telecommunications, computer systems, or non-surgical outpatient services not part of an otherwise reviewable project and whose capital cost does not exceed 20% of the hospital's gross annual patient revenue for its last fiscal year).

[214]*See supra* note 159 and accompanying text.

[215]ALA. CODE § 22-21-275(4) (Supp. 1984) (non-substantive review of capital expenditures up to $500,000 which: do not result in a substantial change in a service; or propose equipment to upgrade or expand an existing service; or increase bed capacity by not more

states without specific statutory procedures for expedited review have

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than ten percent); ARIZ. REV. STAT. ANN. § 36-433(G) (Supp. 1984) (abbreviated application for all projects except establishment of new services with annual operating costs exceeding $75,000; construction of new health care facilities; and capital expenditures, other than expenditures for equipment replacement, exceeding $150,000); CAL. HEALTH & SAFETY CODE § 437.15 (Deering Supp. 1985) (expeditious processing of applications for projects for sole community provider hospitals with less than 100 beds; projects for skilled nursing or intermediate care facility establishment, projects for addition of skilled nursing or intermediate care beds in facilities other than skilled nursing or intermediate care facilities); FLA. STAT. ANN. § 381.494(1)(n) (West Supp. 1985) (expedited review of transfer of a certificate of need); GA. CODE ANN. § 31-6-47(c) (1985) (statutory authorization for SHPDA to conduct expedited review of projects, where compatible with statutory purposes); IOWA CODE ANN. § 135.67 (West Supp. 1984-85) (summary review procedures for projects costing $150,000 or less; and projects for which the applicant, the state agency, and the HSA agree to summary review); KY. REV. STAT. § 216B.095 (Supp. 1982) (non-substantive review of applications to replace or repair five-year-old worn equipment; repairs, alterations, or improvements to physical plant not resulting in a substantial change in beds/services or equipment addition; and other applications as prescribed by state agency regulations); ME. REV. STAT. ANN. tit. 22, § 304-C (Supp. 1985-86) (waiver of review of new health services projects involving a capital expenditure below $300,000, third year annual operating costs between $155,000 and $250,000 and no increase in reimbursement authorization by rate-setting commission); MICH. COMP. LAWS ANN. § 333.22151 (1980) (non-substantive review of projects for which full review could increase cost by unnecessary delay or require inefficient use of staff review time); MISS. CODE ANN. § 41-7-205 (Supp. 1984) (non-substantive review of: certain transfers of ownership; replacement of equipment; general-purpose capital expenditures not exceeding $700,000; acquisition of major medical equipment not exceeding $460,000; certain project cost overruns; and deletion or relocation of services or facilities); MO. ANN. STAT. § 197.305(12) (Vernon Supp. 1985) (non-substative review of capital expenditures due to an act of God or a normal consequence of maintaining health care services, facilities, or equipment which do not involve bed addition, replacement, modernization, conversion, or new services); MONT. CODE ANN. § 50-5-302 (Supp. 1984) (abbreviated review of proposals that do not significantly affect the cost or use of health care or that have been approved by the legislature); NEB. REV. STAT. § 71-5834 (Supp. 1984) (non-substantive review of replacement of equipment with equipment of similar capability; reduction in bed capacity or termination of a single service which does not involve the closing or relocation of a health facility; expenditures for energy conservation proposals); 1984 Ohio Legis. Bull. § 3702.52(J) (Anderson) (expedited review of: capital expenditures less than $1.5 million not involving bed or service additions, equipment acquisition, new facility construction, or facility category conversion; additions of new services with capital costs less than the expenditure care minimum, annual operating costs less than $500,000 and no bed additions; non-patient-related capital expenditures not affecting patient charges; bed capacity increases or redistributions up to nine beds or ten percent of bed capacity (or bed relocations), whichever is less, in any two year period, and not involving a health service addition or a capital expenditure exceeding the expenditure minimum; acquisition of medical equipment for less than $1.25 million; replacement of medical equipment for less than $1.5 million; and other projects specified by regulation); OR. REV. STAT. § 442.320(b) (Supp. 1983) (statutory authorization for adoption of rules providing for accelerated review of expenditures for repairs and replacement of plant or equipment; non-clinically related capital expenditures, and offering or development of a new health service of a non-substantive nature); PA. STAT. ANN. tit. 35, § 448.702(j)(2) (Purdon Supp. 1984-85) (exemption from comparative review requirements for replacement of equipment not involving a substantial change in functional capacity or capability; energy-saving equipment installations or renovations not

adopted such mechanisms by regulation.[216] Several states provide for exemption or expedited review of projects for replacement of facilities or equipment.[217] A few have implemented the NHPRDA exemption for

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involving new services or expansion of capacity); R.I. GEN. LAWS § 23-15-5 (Supp. 1984) (statutory authorization for adoption of regulations specifying projects eligible for expenditious review); S.D. CODIFIED LAWS ANN. § 34-7A-39 (Supp. 1984) (abbreviated review of projects which: increase bed capacity, redistribute beds among categories, or relocate beds from one facility to another, by less than ten beds or ten percent of bed capacity; capital expenditures to remedy emergency situations; and other projects declared eligible for abbreviated review by regulation); W. VA. CODE § 16-2D-7(v) (Supp. 1984) (statutory authorization for adoption of regulations specifying applications eligible for expedited review); WYO. STAT. § 35-2-206(c) (1977) (department review of temporary addition or subtraction of beds or equipment and replacement services or expenditures which are comparable and necessary to maintain services).

[216]*E.g.*, IDAHO ADMIN. PROC. MANUAL tit. 2, § 16.02, 11300, 02 (1983) (non-substantive section 1122 review of repair or replacement of physical plant and equipment associated with physical plant, *i.e.*, boilers, air conditioning, electrical circuitry); DIVISION OF POLICY, PLANNING & EVALUATION, OFFICE OF MANAGEMENT & FINANCE, LA. DEP'T OF HEALTH & HUMAN RESOURCES, POLICIES AND GUIDELINES FOR REVIEW OF CAPITAL EXPENDITURES UNDER SECTION 1122 OF THE SOCIAL SECURITY ACT 6-7 (1985) (expedited section 1122 review of replacement or modification of equipment, sale of an existing facility with no change in beds or services, lease (or discontinuance of a lease) of an approved existing facility with no change in beds or services, renovation of an existing facility up to $1,000,000 not resulting in a bed or service change; cost overrun; addition of non-medical equipment or purchase of land; addition of a new service in an existing facility not exceeding $600,000; incorporation, reorganization, merger, consolidation, majority stock sale or transfer or other changes in the person owning an approved facility; non-substantial site change; bed capacity reduction; and discontinuance of an approved service); N.J. ADMIN. CODE tit. 8, § 33-2.5 (1985) (administrative review of increase in residential health care facility beds of ten beds or ten percent of licensed capacity, whichever is less; change in bed category not involving a capital expenditure or an increase in total licensed capacity, additions of new services, fixed or moveable equipment, or renovations required by law or to prevent harm to patients; transfer of a patient care service in whole or part to another corporate entity; replacement of equipment; acquisition of telephone or computer systems in excess of $400,000; and acquisition of fixed equipment or renovation dealing exclusively with energy conservation); N.Y. ADMIN. CODE tit. 10, § 710.1(c)(3) (1985) (administrative approval of: proposals not exceeding $3 million for addition or modification of a licensed service, with exceptions for certain specialized services; bed or service decertification; certain bed-category conversions, additions to existing services not involving an additional site or beds, projects for correction of safety deficiencies, ordinary repairs, energy conservation, and modernization in facilities for which there is a continuing need; replacement and updating of equipment in needed facilities; addition or deletion of approval to operate part-time clinics; operation or relocation of extension clinics; emergency room modernization; projects identified as high priority in the state medical facilities plan).

[217]GA. CODE ANN. § 31-6-47(a)(10) (1985) (exemption of expenditures for replacement of equipment including but not limited to CT scanners); KY. REV. STAT. § 216B.095 (Supp. 1982) (nonsubstantive review of replacement of equipment used for five years or more and repairs, alterations, and improvements to physical plant not resulting in bed or services changes or equipment additions); MISS. CODE ANN. §§ 41-7-191(2), 205 (Supp. 1985) (exemption from health facility expansion, construction moratorium for necessary repairs and renovation or replacement of an existing facility); MO. ANN. STAT. § 197.305(12)

research projects.[218] The approval rates for projects eligible for expedited review tend to be very high, making expedited review effectively very similar to an exemption from review.

In short, the majority of states have employed exemptions and expedited review to diminish substantially the range of projects subject to review and to focus review on projects for new or significantly expanded clinical service capacity. The practice is not confined to the states with high thresholds. Two of the four states that have retained thresholds at the $100,000 - $200,000 level have adopted some form of expedited review or non-substantive project exemption.[219]

4. Bed-Related Coverage.—All jurisdictions with certificate of need or section 1122 programs cover bed supply increases in some fashion. Even states like California and Colorado, which have sharply cut back on coverage by repealing or greatly increasing expenditure thresholds, continue to review increases in bed capacity. However, over half the states have adopted insubstantial increase exemptions, an increase from the number reported in earlier surveys.[220] Most states use the "ten beds or ten percent" exemption authorized by NHPRDA. California and Georgia exempt "ten beds or ten percent" increases from review only if the facility meets certain occupancy rate minimums,[221] while Colorado exempts from review a twenty bed increase every two years.[222]

Thirty-five states cover some form of bed category conversion or bed relocation, while over half the states cover bed capacity decreases.

(Supp. 1985) (nonsubstantive review of replacement and modernization projects); NEB. REV. STAT. § 71-5835 (Supp. 1984) (nonsubstantive review of equipment replacement); 1984 Ohio Legis. Bull. § 3702.52(J) (Anderson) (expedited review of replacement of equipment under $1.5 million); OR. REV. STAT. § 442.320(a)(b) (Supp. 1983) (accelerated review of repairs or replacement of plant or equipment); PA. STAT. ANN. tit. 35, § 448.702(j)(2) (Purdon Supp. 1984-85) (exemption from comparative review requirements for equipment replacement and renovation to meet code requirements); WYO. STAT. § 35-2-206(d) (Supp. 1985) (expedited review of expenditures for upgrading and replacing equipment, and replacement services or expenditure to upgrade, acquire, or implement new technology which may be comparable and necessary to maintain services); N.J. ADMIN. CODE tit. 8, § 33-2.7(a)(7) (1985) (expedited review of equipment replacement); N.Y. ADMIN. CODE tit. 10, § 710.1(b)(c)(3) (1985) (administrative review of projects under $3 million for modernization of facilities and replacement and updating of equipment for which there is continuing need).

[218]KY. REV. STAT. § 216B.066 (Supp. 1982); MASS. GEN. LAWS ANN. ch. 111, § 25C (West 1983); NEB. REV. STAT. § 71-5830.01 (Supp. 1984); N.C. GEN. STAT. § 131E-179 (Supp. 1983); TEX. REV. CIV. STAT. ANN. art. 4418h, § 3.01(d) (Vernon Supp. 1984); W. VA. CODE § 16-2D-4(c) (Supp. 1984).

[219]Michigan and Rhode Island have adopted expedited review provisions. *See supra* note 215.

[220]*See supra* note 109 and accompanying text.

[221]CAL. HEALTH & SAFETY CODE § 437.11(4) (Deering Supp. 1985); GA. CODE ANN. § 31-6-47(15) (1985).

[222]COLO. REV. STAT. § 25-3-506(e) (1982).

The recent amendments to the NHPRDA regulations permitting complying state certificate of need programs to make their own determinations as to whether to cover such transactions will probably cause a decrease in these figures.

C. Health Service-Related Coverage

Table 3 indicates that all of the states with certificate of need or section 1122 programs cover additions of new health services. Half cover service terminations, but because only nine states cover terminations not associated with a capital expenditure and terminations do not usually involve capital expenditure, actual review of service terminations appears to be a relatively infrequent practice.

Twenty-six states have adopted annual operating cost thresholds.[223] Thresholds vary widely, from $75,000 in Rhode Island to $536,000 in Washington. Just five states, however, cover health service additions only if they are associated with annual operating costs exceeding the threshold.[224] The remaining states either cover health service additions regardless of cost or, following the NHPRDA model, cover health service additions associated with any capital expenditure. Both of the latter approaches appear inconsistent with the policy underlying annual operating cost thresholds, which is to target the cost containment functions of certificate of need while minimizing the scope of coverage by reviewing only those service additions that generate additional long-term costs.[225]

A number of states have adopted a new approach to coverage of health service additions. These states cover additions of a small number of specified new health services regardless of their capital or operating cost, and all other new services only if their capital or operating costs exceed a threshold. For example, Wisconsin covers additions of organ transplant programs, burn centers, neonatal intensive care units, cardiac programs, and air transport programs without regard to cost.[226] Other

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[223]The states differ in the way they define their annual operating cost thresholds. Maine, for example, uses the projected annual operating costs without any adjustment for inflation for the third fiscal year of operation, including a partial first year. "Annual operating costs" are defined as "total incremental costs to the institution which are directly attributable to the addition of a new health service." ME. REV. STAT. ANN. tit. 22, §§ 303(2)(A), 304-A(4)(B) (Supp. 1984-85). The District of Columbia employs an "annual operating budget" threshold, Maryland an "annual operating revenue" threshold. D.C. CODE ANN. § 32-302(12)(D) (Supp. 1984); MD. HEALTH-GENERAL CODE ANN. § 19-115(j)(2)(ii) (Supp. 1985).

[224]Maryland, Missouri, Montana, Oklahoma, and Wyoming.

[225]The statutory certificate of need coverage approach of Montana and Wyoming appears to come the closest to accomplishing this policy. They have relatively high capital expenditure and major medical equipment thresholds and $100,000-$150,000 operating cost thresholds. Under this approach, projects are subject to review only if they increase long-term operating costs or represent high, one-time capital expenditures.

[226]1985 Wis. Legis. Serv. 390 (West) (to be codified at WIS. STAT. §§ 150.61(1),(2)).

hospital service additions are covered only if capital costs exceed $1,000,000.[227] Similarly, Ohio covers additions of heart, lung, liver, and pancreas transplant programs without regard to cost and other new services only if their annual operating costs exceed $297,500.[228] Other states may achieve a similar coverage pattern through exemptions or streamlined review. New York, for example, provides for "administrative approval" of service additions or modifications unless the project cost will exceed $3,000,000 or relates to certain specified service categories.[229] The purpose of this approach seems to be to cover without regard to cost the services for which non-cost containment rationales for certificate of need review apply and to cover the services for which cost-control is the paramount concern only if project costs exceed the threshold. The

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[227] *Id.*

[228] 1984 Ohio Legis. Bull. § 3702.51(R)(2), (9) (Anderson); *see also* ARIZ. REV. STAT. ANN. §§ 36-433(A)(5),(6) (Supp. 1975-84) (repealed 1985) (coverage of additions of obstetrical units, neo-natal special care units, pediatric inpatient services, open-heart surgery units, cardiac catheterization services, radiation therapy services, end-stage renal dialysis services, computed tomographic scanning, neurological units, spinal injury units, and burn treatment units regardless of cost, and additions of other services only if their operating costs exceed $750,000); COLO. REV. STAT. §§ 25-3-503(10), 506(1)(d) (1982) (repealed 1984) (coverage of tertiary services [i.e., highly specialized services frequently requiring sophisticated technology and support services and limited to open-heart surgery, organ transplantation, burn care, level III intensive care nurseries, and radiation therapy] at any cost, and coverage of only those other services exceeding threshold); ILLINOIS HEALTH FACILITIES PLANNING BOARD, ILLINOIS HEALTH CARE FACILITIES PLAN § 3.02.B.29 (1982) (coverage of acute mental illness, alcoholism treatment, burn treatment, cardiac catheterization, computer systems, end-stage renal disease, intensive care, medical-surgical, non-hospital based ambulatory surgery, obstetrical services, open-heart surgery, pediatric services, perinatal high risk, radiation therapy, rehabilitation services additions regardless of cost; other services exceeding annual operating costs threshold); KY. REV. STAT. § 216B.015(25) (Supp. 1982) (coverage of health service additions exceeding $250,000 annual operating cost or additions of services specified in State Health Plan, regardless of cost. The Kentucky State Health Plan provides for coverage of acute care services, open-heart surgery, cardiac catheterization, radiation therapy utilizing megavoltage equipment, end-stage renal disease services, CT scanners, nuclear magnetic resonance imaging, and long-term care services); ME. REV. STAT. ANN. tit. 22, § 304-A(4) (Supp. 1984-85) (coverage of new services regardless of cost identified in regulations or new services exceeding the annual operating cost threshold; no regulations adopted to date); MASS. GEN. LAWS ANN. ch. 111, § 25B (1983); MASS. ADMIN. CODE tit. 105, § 100.020 (1983) (coverage of "major services" without regard to cost and of only those other services exceeding annual operating cost threshold); 1985 Or. Laws, ch. 747 § 16 (to be codified at OR. REV. STAT. § 442.015(24)); OR. ADMIN. R. 409-03-010(10) (1985) (coverage of new health services exceeding annual operating expense threshold or new health services, regardless of cost, which may compromise quality of care); TENN. ADMIN. COMP. § 0720-2-.02(2)(d) (1985) (coverage of specified set of major health services without regard to cost and other services with projected annual operating budget exceeding $500,000 threshold).

[229] Therapeutic radiology, open-heart surgery, cardiac catheterization, kidney and heart transplant, chronic and acute renal dialysis, CT scanning, burn care, and extracorporeal shockwave lithotripsy require approval regardless of cost. N.Y. ADMIN. CODE tit. 10, § 710.1(c)(3) (1985).

Oregon provision does so most explicitly, by covering new services either if they exceed the annual operating expense threshold or may potentially compromise quality of care through insufficient volume to support needed specialized staff or to maintain skills.[230]

NHPRDA and section 1122 left the states free to define which newly-established "services" would be subject to certificate of need review.[231] Most states appear to have never specified in their statutes or regulations the "health services" they subject to review. However, some have done so. The states listed above as covering some specified health service additions regardless of cost, of course, have at least a partial list. In addition, California's certificate of need provisions cross-reference a statutory list of special services subject to health facility licensure.[232] The Georgia statute contains a non-inclusive list of clinical health services subject to review, which corresponds roughly to the major service departments in a typical large hospital.[233] Finally, a few states cover expansions of existing services.[234] However, most cover only service additions.

D. Major Medical Equipment Coverage

In most states, acquisition of medical equipment by or on behalf of a health care facility is subject to certificate of need review as a capital expenditure if the capital expenditure associated with the acquisition exceeds the expenditure threshold.[235] However, the 1979 NHPRDA

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[230] OR. ADMIN. R. 409-03-010 (1985).

[231] *See supra* notes 122-28 and accompanying text.

[232] CAL. HEALTH & SAFETY CODE § 437.10(c) (Deering Supp. 1985).

[233] GA. CODE ANN. § 31-6-2(5) (1985) provides:

> "Clinical health services" means diagnostic, treatment, or rehabilitative services provided in a health care facility, or parts of the physical plant where such services are located in a health care facility, and includes, but is not limited to, radiology; radiation therapy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; dialysis; general medical care; medical/surgical care; inpatient nursing care, whether intermediate, skilled, or extended care; cardiac catheterization; open-heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

See also ALASKA STAT. § 18.07.111(8) (1981) (health service defined as major type, program, unit, division, or department of care, including outpatient, psychiatric wing, kidney dialysis, radiotherapy, burn unit, newborn intensive care unit); R.I. GEN. LAWS § 23-15-2(h) (1979) (health services defined as "organized program components" for providing services); MINN. STAT. ANN. § 145.833 Subd. 3 (West 1982) (repealed 1984) (health services defined as cost centers recognized by generally accepted accounting principles and conforming to cost center definitions used by state rate-setting/price disclosure program).

[234] 1985 Nev. Adv. Sh. ch. 454, § 13 (to be codified at NEV. REV. STAT. § 439A.100(2)(c)); OR. ADMIN. R. 409-03-010(6) (1985).

[235] In some states, the acquisition of certain types of equipment may also constitute a covered addition of a new service. For example, acquisition of a CT scanner constitutes a new service in Arizona and Kentucky. *See supra* note 228.

amendments authorized a distinct category of coverage, acquisitions of medical equipment exceeding an expenditure minimum lower than the all-purpose capital expenditure threshold if the equipment is owned by or located in a health care facility or used to provide services for in-patients.[236] Most states have adopted this coverage category, with statutory equipment thresholds varying from $125,000 to $1,000,000.

Seventeen states cover acquisitions of medical equipment that may be used for persons who are not in-patients of a health care facility. Virginia covers acquisition by a physician's office of equipment that is generally and customarily associated with the provision of health services in an in-patient setting.[237] Fifteen states and the District of Columbia cover equipment acquisitions in various non-in-patient settings.[238] Most of these states added their coverage of equipment in non-institutional settings after witnessing placement of CT scanners and, most recently,

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[236]Pub. L. No. 96-79, § 117, 93 Stat. 592, 615 (1979) (codified as amended at 42 U.S.C. § 300m-3).

[237]VA. CODE § 32.1-102.1 (Supp. 1985).

[238]COLO. REV. STAT. § 25-3-506(1)(g) (Supp. 1985) (capital expenditure exceeding $1 million by or on behalf of any person or entity for major medical equipment to provide clinically related health care); CONN. STAT. ANN. § 19a-155(b) (West Spec. Pamp. 1984) (capital expenditure exceeding $400,000, by any person, to acquire imaging equipment); D.C. CODE ANN. § 32-302(11)(A) (Supp. 1984) (acquisition of medical equipment with a value exceeding $400,000 by physicians, dentists, or other individual providers of individual group practice); HAWAII REV. STAT. §§ 323D-53, 54 (Supp. 1984) (acquisition of equipment exceeding expenditure threshold by physicians' offices); IOWA CODE ANN. § 135.61(19)(g) (West Supp. 1984-85) (expenditure exceeding $400,000 by individual or group of health care providers for equipment installed in private office or clinic); MD. HEALTH-GENERAL CODE ANN. §§ 19-1001 *et seq.* (Supp. 1985) (licensure of major medical equipment wherever located costing in excess of $600,000); MISS. CODE ANN. § 41-7-191(1)(f) (Supp. 1985) (acquisition or control of major medical equipment exceeding $750,000 by any person); MONT. CODE ANN. § 50-5-301(d) (Supp. 1984) (acquisition by any person of medical equipment exceeding $500,00 which would have required a CON if acquired by a health care facility); 1985 Nevada Adv. Sh. ch. 454, §§ 9, 13 (to be codified at NEV. REV. STAT. §§ 439A.015(10), .100(d) (acquisition of medical equipment exceeding $400,000 by the office of a health services practitioner); 1985 N.H. Laws, ch. 378, § 378:6 (to be codified at N.H. REV. STAT. ANN. § 151-C:5(II)(D)) (acquisition of equipment exceeding $400,000 by a health care provider); 1985 N.C. Adv. Legis. Serv., ch. 740, § 6 (to be codified at N.C. GEN. STAT. § 131E-176(16)(g)) (acquisition by any person of major medical equipment that includes magnetic resonance imaging and lithotripters, regardless of ownership or location); 1985 Or. Laws, ch. 747, § 31 (to be codified at OR. REV. STAT. § 442.320(1)(b)) (acquisitions of medical equipment exceeding $1 million by any person); R.I. GEN. LAWS § 23-15-2(k) (1977) (acquisition of medical equipment exceeding $150,000 by a health care provider); W. VA. CODE §§ 16-2D-2t, 16-2D-3(h) (Supp. 1985) (acquisition of major medical equipment exceeding $400,000 by any person); WIS. STAT. ANN. § 150.61(3) (West Supp. 1984) (capital expenditure exceeding $1 million for clinical medical equipment by an independent practitioner or medical group); WYO. STAT. §§ 35-2-202(a)(ix), 205(a)(iii) (Supp. 1985); DIV. OF HEALTH & MEDICAL SERVS., WYO. DEP'T OF HEALTH & SOCIAL SERVS., RULES AND REGULATIONS GOVERNING CERTIFICATE OF NEED, ch. III §§ 2, 4 (1985) (acquisitions of major medical equipment exceeding $400,000 by licensed practitioners' offices).

magnetic resonance imaging (MRI)[239] scanners in physician's offices and other non-institutional settings in order to evade certificate of need review.[240] States that did so after September 1982 not only breached NHPRDA's ban on extension of medical equipment coverage after that date,[241] but they also overcame health planners' traditional reluctance to extend certificate of need regulation into physicians' offices.

E. New Facilities and Acquisitions of Existing Facilities

Over half the states cover construction, development, or establishment of a new health care facility. This coverage provision probably does not trigger review of any projects not otherwise covered as service or bed additions or capital expenditures. It is possible that in states with high expenditure thresholds and a restrictive list of covered new services, establishment of inexpensive, non-bed related facilities like home health agencies and hospices might escape review without such a provision.

NHPRDA does not require states to cover acquisitions of existing health care facilities by individual persons or entities.[242] However, a significant minority of states appears to do so. Mississippi covers acquisitions and forbids any person or entity from acquiring more than twenty percent of all skilled nursing or intermediate care facility beds in the state.[243] Nebraska law contains a similar prohibition, applicable to short-term hospitals as well as to nursing facilities.[244] Twelve other jurisdictions cover acquisitions or transfers of ownership interests in health facilities.[245]

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[239]MRI is a non-radiological diagnostic tool that uses magnetic and radio frequency fields to construct an image of body tissue and monitor body chemistry.

[240]The presence of a certificate of need program covering institutional acquisitions of medical equipment tends to encourage the placement of such equipment in non-institutional settings. Hillman & Schwartz, *The Adoption and Diffusion of CT and MRI in the United States*, 23 MED. CARE 1283 (1985). Whether this represents a success or a failing of certificate of need depends on one's calculation of the relative costliness and medical appropriateness of the equipment in the two settings.

[241]42 U.S.C. § 300m-6(e)(1)(B) (1982).

[242]*See supra* note 97 and accompanying text.

[243]MISS. CODE ANN. §§ 41-7-191(1)(b), 41-7-190 (Supp. 1984-85).

[244]NEB. REV. STAT. §§ 71-5830(l) (Supp. 1984).

[245]D.C. CODE ANN. § 32-303(c) (1981); HAWAII REV. STAT. § 323D-43(a)(1) (Supp. 1984); KY. REV. STAT. ANN. § 216B.061(b) (Supp. 1982); ME. REV. STAT. ANN. tit. 22, § 304-A(3) (Supp. 1984-85); 1985 N.H. Laws, ch. 378, § 378:6 (to be codified at N.H. REV. STAT. ANN. § 151-C:(II)(b)); N.J. STAT. ANN. § 26-2H-7 (Supp. 1984-85); OKLA. STAT. ANN. § 2651.1(2)(d) (Supp. 1984); S.C. CODE ANN. § 44-7-320 (Law. Co-op Supp. 1983); W. VA. CODE § 16-2D-3 (Supp. 1985); WIS. STAT. ANN. § 150.61(4) (West Supp. 1985); GA. ADMIN. COMP. ch. 272-2, §§ 272-2-.01(17)(b),(g) (1982) (coverage of capital expenditure to acquire a health care facility under section 1122 and, for publicly owned or operated facilities, under certificate of need); LOUISIANA DEP'T OF HEALTH & HUMAN RESOURCES, POLICIES AND GUIDELINES FOR REVIEW OF CAPITAL EXPENDITURES 5 (1985); MAINE CERTIFICATE OF NEED REGULATIONS, ch. 4, § 7 (1984).

F. Modifications in Certificate of Need Review Procedures

As well as reducing certificate of need coverage requirements, states have been modifying the certificate of need review process. Some states have attempted to distill their review criteria down to a few critical considerations. New Hampshire, for example, recently amended its law to substitute the four criteria of financial feasibility, availability of resources, access, and quality for its previous laundry list of over twenty considerations.[246] Other states have assigned priorities to their criteria.[247]

A recurrent predicament for certificate of need agencies is the receipt of applications for new types of equipment or services of unproven clinical efficacy. For example, planning agencies received numerous applications for MRI scanners well before the Food and Drug Administration had issued premarket approval for their sale.[248] Lacking standards on which to base decisions in these situations, planning agencies have tended either to adopt delaying tactics or to deny applications without properly-adopted criteria, both with disastrous results; or simply to approve all applicants.[249] More recently, however, some agencies have obtained authority to impose moratoria on review of applications for new, untested technology or to establish other limits regarding innovations. West Virginia's statute, for example, empowers the state agency to order a ninety-day moratorium on processing applications for new medical technology when criteria and guidelines for evaluating the need for the new technology have not yet been adopted.[250] Ohio's law authorizes the state agency to condition approval of projects for tech-

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[246]*Compare* 1985 N.H. Laws, ch. 378, § 6 (to be codified at N.H. REV. STAT. ANN. § 151-C:7) *with* N.H. REV. STAT. ANN. § 151-C:6 (Supp. 1983); *compare also* HAWAII REV. STAT. § 323D-43(b) (Supp. 1984) (review criteria of public need, cost and cost effectiveness, and consistency with state health plan) *with* HAWAII REV. STAT. § 323D-43(b), (C)(1)-(25) (Supp. 1983); TENN. CODE ANN. § 68-11-106(h)(2) (Supp. 1985) (criteria of area-wide need, economical cost, and contribution to orderly development of adequate facilities and services) *with* TENN. CODE ANN. §§ 68-11-106(h)(1)(A)-(M) (Supp. 1983).

[247]*E.g.*, OKLA. STAT. ANN. § 2652.1(c) (West 1984) (planning agency authority to establish relative weights of statutory certificate of need criteria); WIS. STAT. ANN. § 150.69 (West Supp. 1985) (cost containment identified as first priority in applying criteria).

[248]OFFICE OF HEALTH PLANNING, U.S. DEP'T OF HEALTH & HUMAN SERVICES, SUMMARY REPORT OF RESPONSES TO NUCLEAR MAGNETIC RESONANCE INFORMATION REQUEST, PROGRAM INFORMATION LETTER 83-23 (1983).

[249]*See* Florida Medical Center v. Department of Health & Rehabilitative Servs., 463 So. 2d 381 (Fla. Dist. Ct. App. 1985) (MRI denial based on unpromulgated criteria reversed); United Hosp. Center, Inc. v. Richardson, 328 S.E.2d 195 (W. Va. 1985) (refusal to process MRI application enjoined).

[250]W. VA. CODE § 16-2D-5(f) (Supp. 1985); *see also* D.C. CODE ANN. § 32-314 (1981) (authorization for 120-day moratorium on certificate of need review of new service if state agency requires additional time to develop and adopt criteria); 1985 N.H. Laws, ch. 378, § 6 (to be codified at N.H. REV. STAT. ANN. § 151-C:4) (prohibition on issuance of certificate of need for service for which state agency has not adopted criteria).

nologically innovative medical equipment on the applicant's agreement to supply the agency with data to establish the equipment's clinical efficacy.[251]

States with health facility rate regulation programs have taken steps to coordinate the decisions of certificate of need and rate-setting agencies. Washington, for example, requires determination of the financial feasibility and cost impact of hospital certificate of need applications by the state's hospital commission, a rate-setting agency, and absent special findings, mandates denial of an application disfavored by the commission.[252] Finally, planning agencies throughout the country are increasingly basing their certificate of need decisions on the project's consistency with state health plans.[253] In part because certificate of need decision-making has become more plan-driven and in part as a result of planning agencies' accumulated experience with administrative adjudication, certificate of need decisions are now seldom overturned for lack of substantive validity.[254]

A substantial number of states have imposed moratoria on some or all certificate of need applications or approvals in recent years. The

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[251]1984 Ohio Legis. Bull. file 234, § 1 (Anderson) (to be codified at OHIO REV. CODE ANN. § 3702.53(E)(5)); *see also* IOWA CODE ANN. § 135.64(3) (Supp. 1985) (certificate of need criterion establishing special consideration for university hospitals with respect to technologically innovative equipment and services); ME. REV. STAT. ANN. tit. 22, § 309(2)(m) (1980) (certificate of need criterion of need for utilizing new technological developments on a limited, experimental basis); WIS. STAT. ANN. § 150.63 (West Supp. 1985) (certificate of need exemption for research, development, and evaluation of innovative medical technology).

[252]WASH. REV. CODE ANN. § 70.38.115(2)(d) (Supp. 1986); *see also* 1985 Wisc. Legis. Serv. 29 § 1980p (West) (to be codified at WIS. STAT. ANN. § 150.69d(5)) (hospital rate-setting commission to provide analysis of reasonableness of certificate of need applicant's proposed costs and charges).

[253]*E.g.*, Princeton Community Hosp. v. State Health Planning & Dev. Agency, 328 S.E.2d 164 (W. Va. 1985).

[254]*See, e.g.*, Humana Medical Corp. v. State Health Planning & Dev. Agency, 460 So. 2d 1295 (Ala. Civ. App. 1984) (area bed supply excess supports denial on need and cost containment criteria); Humana, Inc. v. Department of Health & Rehabilitative Servs., 469 So. 2d 889 (Fla. Dist. Ct. App. 1985) (quality of care considerations supported need methodology prohibiting new cardiac catheterization facilities until existing facilities were fully utilized); Mercy Health Center v. State Health Facilities Council, 360 N.W.2d 808 (Iowa 1985) (denial of application on ground of cross-subsidization of non-health care services upheld); *In re* Certificate of Need Application by Community Psychiatric Centers, Inc., 234 Kan. 802, 676 P.2d 107 (1984) (determination of need on areawide basis upheld); Beatrice Manor, Inc. v. Department of Health, 219 Neb. 141, 362 N.W.2d 45 (1985) (planning agency policy to encourage non-institutional care justified denial of crowded nursing home's application to add beds); Chambery v. Axelrod, 101 A.D.2d 610, 474 N.Y.S.2d 865 (1984) (certificate of need preference for facilities participating in Medicaid upheld); Humana Hosp. Co. v. Oklahoma State Health Planning Comm'n, 705 P.2d 175 (Okla. 1985) (lack of need as measured by state health plan formula justified certificate of need denial).

primary reason for doing so has been to bar new services or expansion in areas in which state plans project no community need for an extended period of time. Missouri, for example, has adopted a moratorium on issuance of certificates of need for new skilled or intermediate care nursing facility beds until July 1, 1988.[255]

Several states have recently resuscitated a proposal that was a key element in the unsuccessful national hospital cost containment strategy of the Carter administration: imposition of a ceiling or "cap" on the total dollar value of projects approveable through certificate of need programs in a given year.[256] A capital ceiling is a mechanism for controlling the total level of capital investment by health facilities for large projects and for compelling health planning agencies to weigh the relative merits of disparate projects.[257] In the presence of a "cap," projects for remodeling existing facilities compete with new construction, and for example, a new open heart surgery service must vie with a new renal dialysis unit for limited capital funds. By contrast, under conventional certificate of need programs, only contemporaneously-filed applications for similar projects are comparatively reviewed.[258] A statutory cap is in operation in Rhode Island and Maine.[259] The Massachusetts hospital rate-setting statute has a maximum on increases in operating costs resulting from capital expenditures.[260] Oregon's law provides for the establishment of a non-enforceable annual capital expenditure target for all hospitals in the state.[261]

VI. The Future of Certificate of Need

State certificate of need and section 1122 capital expenditure review programs have changed significantly over the two decades they have

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[255] Mo. Ann. Stat. § 197.315(1) (Vernon Supp. 1985); *see also* Miss. Code Ann. § 41-7-191(2) (Supp. 1985) (moratorium on nursing home bed increases); 1985 Wis. Legis. Serv. Act 29, § 1980p (West) (to be codified at Wis. Stat. Ann. § 150.62) (moratorium on new hospital establishment or relocation). *See generally* Office of Health Planning, U.S. Dep't of Health & Human Services, Moratoria: A Continuing Process in Regulatory Review, Prog. Inf. Letter 85-32 (1985) (twenty-two states imposed moratoria at some time during 1980-85). For an article reporting on the success of a moratorium in limiting the diffusion of CT scanning, see Lawthers-Higgins, Taft & Hodgman, *The Impact of Certificate of Need on CT Scanning in Massachusetts*, Health Care Mgmt. Rev., Summer 1984, at 71.

[256] *See* D. Abernathy & D. Pearson, Regulating Hospital Costs: The Development of Public Policy 90-92 (1979).

[257] *See generally* Institute for Health Planning, Methods for Establishing Capital Expenditure Limits (1984).

[258] *See, e.g.*, Bio-Medical Applications of Clearwater v. Department of Health & Rehabilitative Servs., 370 So. 2d 19 (Fla. Dist. Ct. App. 1979) (comparative review of "mutually exclusive" kidney dialysis center CON applications required).

[259] Me. Rev. Stat. Ann. tit. 22, § 396-k (Supp. 1985).

[260] Mass. Gen. Laws Ann. ch. 6A, § 32 (West Supp. 1985).

[261] 1985 Or. Laws ch. 747, §§ 21-24.

been in operation. They were initially conceived as an adjunct to community-wide health planning. Later, they were seen as a vehicle for implementation of federal health policy. Today, such programs appear increasingly tailored to fit narrowly-drawn individual state regulatory policies and to compensate for specified market defects.

The persistence of certificate of need regulation in the face of widely-reported studies questioning its efficacy and open hostility from the Reagan administration may seem somewhat surprising. However, research on certificate of need programs has universally assumed that cost-containment was the only purpose of such programs (largely because cost control became the dominant rationale for federal funding for state certificate of need by the mid-70's). This Article has suggested that cost control may be only one of several mixed roles played by state health planning and certificate of need programs. In addition, anecdotal evidence at the state level on the impact of the program on the scope and direction of hospital and other health facility capital investment has never been lacking. Finally, there has probably been a greater awareness at the state level than in the federal government that because certificate of need programs require several years to develop review criteria and administrative procedures needed to function effectively and to survive judicial scrutiny, they could not be evaluated simply on the basis of their first few years of operation.

A. Future State Participation in Certificate of Need

As indicated above, every state except Arizona, Utah, and Texas currently has some form of health facility capital expenditure regulation, whether certificate of need, section 1122, a moratorium, or some combination of these provisions. Eight states' certificate of need laws are scheduled to sunset essentially in their entirety in subsequent years. In addition, two states' laws would expire if NHPRDA were repealed.[262] If all the statutes scheduled to expire (including those linked to NHPRDA repeal) did so and no state entered into a new section 1122 contract or adopted a moratorium, thirty-seven states and the District of Columbia would continue to have some form of capital expenditure review. Thirty-two states and the District of Columbia would have certificate of need statutes, slightly more than had such programs immediately prior to the passage of NHPRDA.

What prompted the states that repealed certificate of need programs to do so? The primary consideration has been recent changes in the

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[262]The Arkansas statute would automatically expire if NHPRDA were to expire or terminate, or if the programs instituted pursuant to NHPRDA ceased to function. ARK. STAT. ANN. § 82-2313.1 (Supp. 1983). The Colorado statute would sunset after the first state legislative session commencing after Congress repealed the state certificate of need requirements of NHPRDA. COLO. REV. STAT. § 25-3-521 (1982).

sources of imperfection in the institutional health services market. As indicated above, the Medicare program has begun to substitute reimbursement at a predetermined rate for incurred-cost payment, and both state Medicaid programs and private health insurers are following suit.[263] The new prospective payment mechanisms, which typically pay individual providers prior-year average costs incurred by all providers, offer a disincentive to above-average cost care and an efficiency incentive in the form of an opportunity to profit from providing below average cost care. There has also been a significant increase in patient enrollment in health maintenance organizations and other health care delivery systems that operate with internal incentives to reduce costs, and some evidence of price competition among such systems and between them and conventional health insurance.[264] For these and other reasons, utilization of institutional health services has been declining, and as with other areas of the economy, the annual rate of increase in health care expenditures has declined. These factors, combined with a general preference for unregulated markets and exasperation with the controversy that often surrounds certificate of need decisions, seem to have prompted the legislatures to repeal certificate of need statutes.

Over half the states repealing certificate of need hedged their bets on deregulation by retaining or re-entering the section 1122 program or adopting construction moratoria. In these states and others that considered but did not repeal certificate of need, there was considerable concern that the increased competitiveness of the institutional health care market had not reached the point at which it would counteract still-existing incentives to capital expansion. An important issue for states was the effect certificate of need repeal itself would have on health facility capital investment and construction. State legislatures, especially those concerned about current spending under Medicaid programs, were concerned with the potential for a large increase in spending immediately after repeal.[265] Evidence from the states that have removed all restrictions on health facility capital investment strongly suggests that a short-term surge does take place when certificate of need controls are lifted.[266]

In Arizona, the certificate of need law expired March 16, 1985.[267] In the six months following, hospitals in Arizona obtained licensure permits for expansion projects, formerly subject to certificate of need

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[263] *See supra* notes 185-91 and accompanying text.

[264] *See, e.g.*, Taylor & Kagay, *The HMO Report Card*, 5 HEALTH AFF. 81, 82 (1986).

[265] A small increase seems almost inevitable, as a consequence of implementation of projects delayed in anticipation of repeal, projects commenced promptly in expectation of reimposition of certificate of need, and the increased attractiveness of the state over still-regulated jurisdictions to new entrants.

[266] *See infra* notes 267-71 and accompanying text.

[267] 1984 Ariz. Sess. Laws ch. 1, § 1.

review, with a total cost of $135 million. By contrast, for the same six-month period in 1984, during which certificate of need review was in effect, hospitals were issued permits for only $7.5 million worth of projects.[268] A total of 674 new hospital beds was included in the 1985 projects, and four new open-heart surgery services were instituted.[269]

Post-repeal expansion also does not seem to taper off after a few months. In Arizona, certificate of need review for nursing homes expired in July 1982. During the subsequent three and one-half year period, the number of facilities and beds in the state increased at a continuous rate. Overall, the number of nursing home beds in the state increased by 51.1%, compared to a 55.8% growth in the preceding nine year period (1974-82) during which certificate of need review was in effect.[270]

Post-repeal expansion appears to be taking place in Utah as well as in Arizona.[271] It seems unlikely that the high level of expansion in Arizona and Utah will continue over the long-term. However, the experience in these states does suggest that certificate of need repeal leads to a short-term increase in construction and expansion whose effects upon excess capacity and costs will linger for years. It also suggests that the recent changes in health facility reimbursement, utilization, and delivery have not purged the institutional health care sector of expansionist tendencies.

The dramatic increases in health facility capital spending in the states that have repealed certificate of need programs will probably discourage a major repeal trend in the remaining states. Of course, the fate of state certificate of need programs is likely to be heavily influenced by

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[268]G. Heller & M. Chase, A Study of the Impact of Health Care Deregulation on Hospitals, Nursing Homes and Health Services in Arizona 242 (report prepared by Office of Planning and Budget Development, Ariz. Dep't of Health Services, Nov. 15, 1985).

[269]The post-repeal expansion does not appear to be attributable to relaxation of overly restrictive prior controls. In 1984, Arizona hospitals had a 57.8% occupancy, well below national averages and guidelines, and an estimated excess capacity of 2,800 beds. Arizona Statewide Health Coordinating Council, Draft Arizona State Health Plan, ch. 10, Appendix A (1985) (1984 Arizona non-federal hospital occupancy rate). *Compare* 42 C.F.R. § 121.202 (1985) (National Guidelines for Health Planning recommended non-federal hospital occupancy rate of 80%); American Hosp. Ass'n, Hospital Statistics 22 (1985) (1984 U.S. non-federal hospital occupancy rate of 71.9%); Arizona Statewide Health Coordinating Council, Current Status/Trends in Arizona's Acute Care Nonfederal Hospital Beds (1984) (1984 excess bed capacity estimate).

[270]G. Heller & M. Chase, *supra* note 268, at 2.

[271]One month after the repeal of Utah's certificate of need law on December 31, 1984, six new hospitals, all previously disapproved under the certificate of need law, were under construction. *Congress Ends Federal Health Planning*, Medicine & Health Perspectives 3 (Oct. 6, 1986). Within a few months after repeal, building permit application had been filed for 2,800 new nursing home beds. Telephone interview with Steven Bonney, Executive Director, Utah Health Systems Agency, May 28, 1985.

the status of NHPRDA and section 1122. Nevertheless, it appears that in the forseeable future, capital expenditure review will continue in the majority of states.

B. Future of State Certificate of Need Programs

Since the relaxation of NHPRDA requirements in 1982, state certificate of need programs have changed considerably. It is likely that the direction and pace of these changes will continue. It seems likely that to the extent states use certificate of need as a mechanism for controlling increases in institutional health care costs, they will increasingly focus certificate of need review on health facility expansions and service additions that generate increased operating expenses. It is these costs, not the capital costs associated with such projects, that have the greatest impact on total costs.[272] Consistent with this focus, one would expect states to increase capital expenditure thresholds, to delete coverage of capital expenditures in any amount for service additions or bed increases, and to retain coverage of service additions or expansions associated with additional annual operating costs. Exemption of the various ambulatory and low-intensity in-patient facilities whose services represent a fraction of total institutional health care costs could also be expected. The recently-amended Indiana certificate of need law seems to follow this approach to an extent. All outpatient facilities, including ambulatory surgery facilities and freestanding hemodialysis units, have been deregulated.[273] Coverage is limited to capital expenditures exceeding $750,000 and to certain bed capacity and category changes affecting beds certified to participate in Medicare or Medicaid.[274]

It also seems likely that states will continue to employ certificate of need review as a vehicle for preserving quality of care by restricting entry to new services having a reasonable probability of meeting minimum volume standards. With an increasingly competitive institutional health care environment and with the potential for large profits from at least some high-intensity, high-technology services, the rationale for this kind of quality-related certificate of need regulation is as great as ever.[275] It

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[272]*See supra* note 146 and accompanying text.

[273]IND. CODE § 16-1-3.3-1 (Supp. 1985). Indiana's law does not, however, provide for coverage of new services not associated with high capital expenditures but with high annual operating costs, e.g., new open-heart surgery services. Compare the Montana and Wyoming coverage patterns discussed *supra* at note 215 and accompanying text.

[274]IND. CODE § 16-1-3.3-1 (Supp. 1985).

[275]The objection is sometimes raised that quality-related regulation should be the domain of facility licensure, not certificate of need. But as the creators of such regulatory regimens, states ought to be free to assign them such roles as they please, irrespective of their labels. Health planning agencies have both the technical tools and the jurisdiction to review the expected utilization of newly proposed services through certificate of need

applies, however, only to a limited set of services which are almost exclusively provided in a hospital setting. States adding the quality-related function to certificate of need programs primarily focused on cost containment can be expected to include in their coverage provisions additions of those specified new services, regardless of capital or operating cost, for which there is a demonstrable relationship between volume and patient outcome. Oregon's newly amended statute, which contains a $1,000,000 capital threshold and coverage of new services that exceed the annual operating cost threshold or are identified with volume-related quality concerns, exemplifies this approach.[276] Alternatively, a state that abandoned certificate of need as a cost containment mechanism but wished to maintain limited entry controls for quality of care purposes might limit its coverage to new hospital services. California's hospital coverage provisions, which exempt all capital expenditures and service additions except for radiation therapy units, burn centers, emergency centers, psychiatric services, newborn intensive care nurseries, cardiac surgery units, and cardiac catheterization units, may reflect this approach.

In recent years, a number of states have increased the role played by certificate of need review in assuring access to institutional health care by persons unable to pay, through preferential treatment of charitable facilities or by outright indigent care quotas.[277] This strategy has attracted attention in other states.[278] However, there is even greater interest at present among the states in programs that redistribute revenues from low indigent care facilities to those treating a disproportionate share of such patients.[279] Typically, such programs authorize a tax on hospital sales or revenues that funds an indigent care account from which facilities with disproportionate indigent care loads may draw.[280] These programs may offer a more precise matching of the benefits or subsidies to a facility with its indigent care burden than certificate of need preferences or quotas. However, these programs may tend to concentrate indigent patients in a limited number of facilities more than certificate of need preferences or quotas do. The redistribution programs are not inconsistent

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programs, while licensing agencies have traditionally fulfilled the role of monitoring the ongoing operations of existing facilities and services. Certificate of need programs can do little in the way of monitoring facility operations, except through enforcement of licensure determinations in subsequent certificate of need proceedings.

[276]*See supra* note 228.

[277]*See supra* note 25.

[278]*See, e.g.*, Subst. S.B. 4403, 48th Wash. Legis., 1984 Reg. Sess. § 22(2)(k), which adopted a certificate of need requirement that each applicant meet or exceed the regional average level of charity care (subsequently vetoed by the governor).

[279]ACADEMY FOR STATE & LOCAL GOV'T, ACCESS TO CARE FOR THE MEDICALLY INDIGENT: A RESOURCE DOCUMENT FOR STATE AND LOCAL OFFICIALS 54-71 (1985).

[280]M. KING, ALTERNATIVE FUNDING SOURCES FOR CARE OF THE MEDICALLY INDIGENT 3 (Nat'l Conf. of State Legislatures 1986).

with certificate of need preferences or quotas. Given the high level of public concern with indigent care and the availability of more direct mechanisms for increasing indigent care access, it seems unlikely that states will make indigent patient access the dominant function of certificate of need programs, but equally likely that it will continue to be one of several functions of such programs.

Employment of certificate of need review as an adjunct to state programs regulating or reimbursing the operating expenses of health facilities is likely to continue as long as states continue to have such programs. However, the number of states with rate regulation programs shows no signs of increasing, and numerous states have changed their Medicaid reimbursement formulae in ways that reduce the incentives to overinvestment and correspondingly reduce the need for compensatory regulatory programs.[281]

C. The Future of Federal Health Planning Law

In the fall of 1986, Congress finally reached the decision to discontinue NHPRDA funding.[282] Congress also passed and sent to the President legislation that would repeal NHPRDA.[283] The possibility of any continued federal funding for state certificate of need and capital expenditure review programs turns on the outcome of the debate over in-patient hospital reimbursement for capital expenditures under the Medicare program. Congress has given itself until October 1, 1987, to devise a mechanism for incorporating payment for such costs into the prospective payment system.[284] Even if it does so, Congress could choose to retain section 1122 either as a mandatory or as a state optional program. However, if Congress succeeds in enacting a new capital reimbursement formula that rewards efficient operations and prudent investment, that maintains an adequate capital plant to assure the long-term availability of hospital services to the increasing Medicare population, and that satisfies budget constraints, it is unlikely that federal interest in supporting state regulatory health planning through section 1122 will continue. Congress might logically conclude that any increment in cost-saving benefits to the Medicare program from state section 1122 programs above and beyond the cost-containment incentives of the prospective payment system would be outweighed by the programs'

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[281] *See supra* notes 185-89 and accompanying text.

[282] Congress' decision took the form of a refusal to include funding for NHPRDA Programs in the 1987 fiscal year continuing resolution, terminating NHPRDA funding as of the end of the 1986 fiscal year (Oct. 1, 1986). *See Congress Ends Federal Health Planning*, MEDICINE & HEALTH PERSPECTIVES, Oct. 6, 1986, at 1.

[283] *See Congress' Health Leaders Agree to Health Legislation Package*, MEDICINE & HEALTH, Oct. 20, 1986, at 3.

[284] Pub. L. No. 98,369, § 2312(c), 98 Stat. 494 (1984).

undesirable enfranchising effect. Congress might also conclude that the benefits of state capital expenditure review programs (both in the area of cost-containment and in the quality of care and access arenas) accrue primarily to states which, on that account, ought to shoulder all or most of the cost of such programs.

Another alternative deserves consideration. The section 1122 program could be retained, but put to a different use. Federally-funded health planning had its origins in planning for the disbursement of federal health facility construction funds through the Hill-Burton program.[285] Today the federal government no longer provides direct support for private health facility construction, even though many of the hospitals and other facilities built with Hill-Burton monies are in need of replacement.[286] Nor is it likely that grants or loans for hospital construction will be reinstituted in the forseeable future. Instead the federal government will support health facility construction primarily through tax exemptions for interest on certain bonds issued for health facility construction[287] and by Medicare reimbursement for capital costs. Both of these supports may be targeted for curtailment in the interest of deficit reduction. Yet it is through the provision of adequate support for health facility capital investments that the Medicare program is assured of the long-term availability of an adequate supply of health care facilities to meet the needs of the Medicare population.

The Medicare program could employ the section 1122 review process to support selected health care facilities in each state and local community that are likely to be needed in the long run to assure the availability of services to Medicare beneficiaries. Health care facilities seeking to make major capital expenditures for replacement or new construction would apply for approval under the section 1122 process.[288] The review would proceed as it has in the past, except that the planning agencies would only determine the need for the proposed expenditure to serve the Medicare population, not the entire community need for the project. Facilities whose projects were identified as needed would be entitled to a Medicare capital allowance in addition to reimbursement for operating expenses associated with treatment of Medicare patients. Facilities not identified as needed would continue to be eligible to participate in Medicare and to receive per-case payment for operating expenses, but Medicare funds would not be given to replace or expand their capital plants.

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[285] *See supra* notes 33-37 and accompanying text.

[286] Ting & Valiante, *Future Capital Needs of Community Hospitals*, 1 HEALTH AFF. 14 (1982).

[287] I.R.C. § 103(a)(1) (1985). *See generally Capital Projects*, 2 TOPICS IN HEALTH CARE FINANCING (Winter 1975).

[288] Minor expenditures, including those associated with moveable equipment acquisitions, could be exempted from section 1122 review and reimbursed through a standard allowance incorporated into the per case payment.

Under this approach, Medicare would selectively support major health facility construction, much as some state Medicaid programs currently contract with a limited group of hospitals or other providers for services to Medicaid beneficiaries, or as Hill-Burton once supported those facilities willing to provide uncompensated care and community service. From a predetermined total federal expenditure for Medicare capital reimbursement, each facility selected for capital payment under this system could receive more generous capital payment than it would receive under a system paying for capital expenses in every Medicare-participating facility.

A simplified version of this process has been proposed. The Office of Management and Budget has suggested that Medicare capital reimbursement to hospitals be limited to those facilities achieving eighty-five percent occupancy rates.[289] The purposes of this approach are to channel Medicare capital reimbursement toward needed facilities, to avoid payment to underutilized, unnecessary facilities, and to permit more generous capital payment within budget constraints by spreading payment over fewer facilities. While the purposes are laudable, a target occupancy rate is a poor substitute for the kind of multi-factored determination of need that health planning programs can make. For example, an eighty-five percent target occupancy rate could penalize small rural hospitals that, although their occupancy rates are low, are needed for reasons of geographical access to services. A high occupancy hospital with a low Medicare patient load might be less deserving of capital support than a lower occupancy facility that treats many Medicare patients. Finally, rather than encouraging closure of excess beds, a target occupancy rate could create an incentive to increase unnecessary admissions and extend hospital stays, contrary to the incentives in the per case system of payment for operating expenses.

Using the section 1122 process to make the federal government a selective investor in health facility capital plants would provide a legitimate participatory role for capital expenditure review in a competitive institutional health services market. It would also reinstitute health planning as a major federal vehicle for management of health care delivery. Medicare is the nation's largest purchaser of institutional health services and few health care facilities do not participate in Medicare. Using health planning agencies operating through the 1122 process as Medicare's purchasing agents would place health planning programs in a central role in determining the allocation of health resources throughout the country.

Whether or not federal funding continues, it appears that a substantial number of states will retain certificate of need programs, at least in the

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[289] WASH. REPORT ON MEDICINE & HEALTH, Dec. 23, 1985, at 3; *see also* 51 Fed. Reg. 19,983 (1986) (HHS request for comments on methods for including adjustment to capital payment for low occupancy hospitals).

near future. It should be apparent that certificate of need regulation continues to satisfy a wide range of state policy roles. However, it also appears that in the absence of federal requirements, a significant number of states will abandon the program in favor of efforts to promote more competitive health service markets. This might well be a fortuitous development. As with any regulatory program that intervenes in the market to accomplish some social good, the necessity for certificate of need programs ought to be continuously evaluated, and the scope of the program tailored to meet specific, concrete, present purposes. It is difficult to do this when the states uniformly adopt the program. The repeal of the program in some jurisdictions provides a natural experiment to measure the impact of the presence or absence of certificate of need review on the direction and scope of health facility expenditures.

APPENDIX

SOURCES: Information contained in the Tables and in this Appendix has been compiled primarily from the author's review of state certificate of need and section 1122 statutes and regulations, supplemented by the author's written and telephonic communications with SHPDA officials, U.S. Department of Health and Human Services officials, and various secondary sources.

EXPLANATORY NOTES: The symbol "X" appearing in the Tables indicates that a particular health care facility or project is subject to certificate of need review in a given state. The symbol "N" appearing in the Tables indicates that additional information regarding a state's coverage of a particular facility or project may be found in the State-by-State Comments section of this Appendix. An asterisk (*) appearing in the "Capital and Other Projects" Table under the coverage categories relating to bed capacity indicates that the state covers the indicated bed-related change only if it exceeds ten beds or ten percent of bed capacity, whichever is less, in any two year period. A dollar amount adjacent to an "X" symbol in the "Capital and Other Projects" Table indicates that the specified project or expenditure is covered only if its cost exceeds the dollar amount.

ABBREVIATIONS USED IN THIS APPENDIX:

AOC = annual operating cost; CCU = coronary care unit; CE = capital expenditure; CON = certificate of need; HHA = home health agency; ICF = intermediate care facility; LF = letter received from; ICU = intensive care unit; LT = letter sent to; MME = major medical equipment; NMR or MRI = magnetic resonance imaging; OAHCF = organized ambulatory health care facility; SHPDA = State Health Planning and Development Agency; SNF = skilled nursing facility; TCF = telephone call from; TCT = telephone call to; 10/10/2 = ten beds or ten percent, whichever is less, in any two-year period; 1122 = section 1122 program.

COVERAGE NOT SHOWN IN THE TABLES: The Tables are intended to comprehensively display the facility and project coverage provisions of state certificate of need and section 1122 programs. A few entities and projects subject to review are not shown. In the "Health Care Facilities, etc." Table, coverage of "persons" is not listed, although virtually all states cover "persons." The "Capital and Other Projects" Table does not list the following transactions, covered under many state CON statutes: (1) Capital expenditure to acquire (either by purchase or under lease or comparable arrangement) an existing health care facility if the person entering into a contractual arrangement for such acquisition does not notify the SHPDA at least thirty days prior to such contractual

arrangement or if the SHPDA finds that the services or bed capacity of the facility will be changed in being acquired. (2) Acquisition of major medical equipment not owned by or located in a health care facility if the person entering into a contractual arrangement to acquire the equipment does not notify the SHPDA at least thirty days before contractual arrangements are made to acquire the equipment. (3) Capital expenditures not otherwise subject to review for proposed changes in previously-approved projects, including cost overruns, and proposed changes not otherwise subject to review in previously-approved projects.

DEFINITIONS OF TERMS IN TABLES:

1. *Definitions used in "Health Care Facilities, etc." Table*: State CON/1122 statutes and regulations employ a variety of definitions and terms to identify the persons and entities subject to CON review. Usually, but not invariably, state statutes first subject "health care facilities" to review and then in statute or regulations list and sometimes define the various types of facilities subsumed under that term. This Table was completed using a standard set of health care facility definitions which does not duplicate any one state's coverage definitions exactly, but which is intended to place comparable types of facilities in distinct categories for comparison purposes. Readers seeking to ascertain whether a particular project would be subject to review in a given state are cautioned to consult the laws of that state. The following definitions apply to the Table: "Hospital" means an institution which primarily provides to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons. The term includes psychiatric and tuberculosis hospitals. Individual states may enumerate other categories of general and specialty hospitals falling within their definition of "hospital". "Skilled nursing facility" means an institution or a distinct part of an institution which primarily provides to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term "intermediate care facility" means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility provides, but who because of their mental or physical condition require health-related care and services (above the level of room and board). The term "medically-oriented residential care facilities" refers to inpatient institutions providing room, board, and personal care services, not including continuous nursing services, to individuals who do not require the degree of care and treatment which a hospital, skilled facility, or intermediate care facility provides but who

by reason of illness, disease, or physical or mental infirmity are unable to effectively or properly care for themselves. The states have various names for these facilities. The term "inpatient rehabilitation facility" means an inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision. The term "home health agency" means a private or public agency or institution, not part of another health care facility, that provides "home health services" as that term is defined in Section 1861(m) of the Social Security Act, or a similar set of services as provided under state law. The term "hospice" means a public agency or private organization not part of another health care facility that provides "hospice care" as that term is defined in Section 1861(dd) of the Social Security Act, or similar care as provided for under state law. The term "kidney dialysis treatment center (including freestanding hemodialysis units)" means a health care facility, not part of another health care facility, which provides dialysis services. "Health maintenance organization (subject to exemption)" means a public or private organization that falls within the health maintenance organization definition in 42 U.S.C. § 300n(8) or a similar definition under state law, and whose capital expenditures and other projects are largely exempt from CON review under state law. "Ambulatory surgery center" means a facility, not a part of another health care facility, which provide surgical treatment to patients not requiring hospitalization. The term does not include the offices of private physicians or dentists, whether for individual or group practice. "Organized ambulatory health care facilities/outpatient clinics" is a generic term encompassing clinics, health centers, and independent facilities other than ambulatory surgery centers, not part of another health care facility, which are organized and operated to provide general outpatient medical care or specific types of medical care to outpatients. The term does not include the offices of private physicians or dentists, whether for individual or group practice. States with broad, general provisions for coverage of OAHCFs but no breakdown or specification of the facilities included thereunder are listed in this category on the Table. A state whose law and regulations provide for both broad, general coverage of OAHCFs and express coverage of specified ambulatory facilities will be checked on the Table both in the "organized ambulatory health care facilities" box and in the boxes corresponding to the specific facilities covered. Some states do not have general coverage of OAHCFs but do cover some specified ambulatory facilities. They are on the Table accordingly. "Freestanding emergicenter" means a facility, not part of another health care facility, which is, or is licensed as, or presents itself to the public as, a 24-hour facility to provide emergency or urgent medical care. "Ambulatory obstetrical facilities/birthing centers" and "family planning/abortion centers" are facilities, not part of another health care facility, pro-

viding some or all such services. "Community health centers/clinics" means neighborhood health centers and community clinics, not part of another health care facility, and in any given state may include "community health centers" falling within the definition thereof in 42 U.S.C. § 254c, "migrant health centers" falling within the definition thereof in 42 U.S.C. §254b, and "rural health clinics" falling within the definition thereof in 42 U.S.C. § 254aa(2). "Public health center" means an official agency established by state or local government, not part of another health care facility, the primary function of which is to provide public health and medical services. "Community mental health centers" means outpatient facilities, not part of another health care facility, which fall within the definition of "community mental health centers" in 42 U.S.C. § 2691 (1973) or a similar definition under state law and includes facilities for treatment of developmental disabilities, mental retardation, alcoholism, drug abuse, chemical dependency and mental illness. "Facilities for the provision of outpatient therapy services including speech pathology" means clinics, rehabilitation agencies, or public health agencies, not part of another health care facility, which provide outpatient physical therapy and speech pathology services as defined in 42 U.S.C. § 1395x(p). "Outpatient rehabilitation facility" means a facility, not part of another health care facility, which provides outpatient rehabilitative services and may include "comprehensive outpatient rehabilitation facilities" as the term is defined in 42 U.S.C. §§ 1395x(cc).

2. *Definitions of projects and capital expenditures in "Capital and Other Projects" Table*: State certificate of need and section 1122 statutes and regulations employ a variety of categories and terms to identify the expenditures, projects, and transactions subject to CON review. Usually, but not invariably, states subject some combination of capital expenditures, additions of new health services and beds, and acquisitions of major medical equipment to review. Most states employ expenditure or annual operating cost thresholds (i.e., dollar values of the amount of an expenditure or major medical equipment acquisition or of the annual operating costs associated with a non-capital expenditure project below which an expenditure or project is not covered). The Table was completed using a standard set of expenditure, project, and transaction definitions which may not duplicate any one state's definitions exactly, but which is intended to place comparable types of expenditures, projects, and transactions in distinct categories for comparison purposes. Readers seeking to ascertain whether a particular project would be subject to review in a given state are cautioned to consult the laws of that state.

Expenditure and project coverage is divided in the Table into two broad categories: coverage of capital expenditures and coverage of projects. The term "general purpose CE/expenditure threshold" refers to coverage of capital expenditures undertaken by or on behalf of health care facilities

for any purpose. If the state employs an expenditure threshold, that threshold is shown. "CE for bed capacity increases and decreases/expenditure threshold" refers to state coverage of applicable expenditures for both increases and decreases in bed capacity of a health care facility. If an expenditure threshold is applied to such coverage, the threshold is shown. "CE for bed capacity increases only/expenditure threshold" is self-explanatory. "CE for changes in bed categories/expenditure thresholds" refers to state coverage of capital expenditures for redistribution of existing health care facility beds among license categories or other services specified under state law. If an expenditure threshold is applied to coverage of such projects, the threshold is shown. "CE for additions of health services/expenditure threshold" refers to state coverage of capital expenditures by or on behalf of health care facilities which are associated with additions of health services which were not offered by or on behalf of the facility within the previous twelve months. If state coverage is dependent on an expenditure threshold, the threshold is given; otherwise health service additions are covered under this category if they are associated with any capital expenditure. "CE for terminations of health services/expenditures threshold" refers to coverage of capital expenditures which are associated with the termination of health services which were previously offered in or through the facility. If state coverage is dependent on an expenditure threshold, the threshold is given in otherwise health service terminations associated with any CE are covered.

Under the listings for coverage of specified projects, "Bed capacity increases and decreases" refers to coverage of both increases and decreases in the total number of beds offered by or on behalf of a health care facility, regardless of whether the change is associated with a capital expenditure. "Bed category changes" refers to coverage of redistribution of beds among various license or other categories under state law, regardless of whether such redistribution is associated with a capital expenditure. "Bed relocations" refers to coverage of relocations of beds from one physical facility or site to another, regardless of whether such relocation is associated with a capital expenditure. "Additions of new health services/annual operating cost threshold" refers to coverage of the addition of a health service which was not offered by or on behalf of a health care facility within the previous twelve months, regardless of whether the addition is associated with a capital expenditure. If coverage of the health service addition is provided for only if the new health service will entail annual operating costs of at least an expenditure minimum for annual operating costs, then the Table indicates the state's annual operating cost dollar threshold. "Termination of a service" refers to a termination of a health service which was offered in or through a health care facility and which is not associated with a capital expenditure. "Acquisitions of major medical equipment/equipment threshold" refers to state coverage of the acquisition by any person of major medical equipment that will

be owned by or located in a health care facility, or equipment that will be used to provide services for hospital inpatients on other than a temporary basis in case of national disaster, major accident, or equipment failure. If the state employs an expenditure threshold for coverage of medical equipment acquisitions, the threshold is shown. "Construction, development, or other establishment of new health care facilities" refers to construction or commencing operation by any person of entirely new physical plants of health care facilities." "Acquisition of existing facilities" refers to the acquisition by any person of the physical plant of an existing health care facility, or the acquisition of the stock or assets of a corporation or other entity owning an existing health care facility. If a state specifies coverage of other projects, the projects are listed in the state-by-state comments.

STATE-BY-STATE COMMENTS TO TABLES:

ALABAMA: *Inpatient rehabilitation facilities, outpatient rehabilitation facilities*: State law provides for coverage of "rehabilitation centers." State regulations provide for coverage of "health facilities required by federal regulations" (which would include inpatient rehabilitation facilities) and "substance abuse rehabilitation facilities" (which may be inpatient or outpatient). *Other entities, persons*: Alabama covers facilities for the developmentally disabled. *CE for other specified purpose*: Alabama statute and regulations cover CE in excess of $245,000 for AOC. Coverage under this provision unclear. *Additions of new health services*: Alabama regulations contain a non-exclusive list of new services subject to review (e.g., (a) ambulance - air unit; (b) ambulance - ground unit; (c) birthing centers and services; (d) nursing home services (ICF and skilled considered as one service); (e) cardiac catheterization (adult or pediatric); (f) angiography laboratory; (g) cardiopulmonary laboratory; (h) ICU/CCU; (i) hemodialysis; (j) hyberbaric chamber; (k) organ transplant; (1) organ bank; (m) open-heart surgery; (n) pulmonary function laboratory; (o) CT scanners (mobile or fixed); (p) nuclear medicine (includes NMR); (q) megavoltage radiation therapy; (r) neonatal intensive care (level II and III); (s) pediatric inpatient services; (t) extracorporeal lithotresis; (u) rehabilitation services (including physical therapy, speech and hearing); (v) psychiatric; (w) substance abuse; (x) specialty services which have been addressed in the appropriate state plan as being properly allocated on a regional basis). *Other specified projects:* Alabama regulations cover "planning, predevelopmental, and developmental activities in excess of $300,000."

ALASKA: *Other entities*: Alaska statute covers "federal hospitals." *CE for bed supply increases and decreases*: Statute covers "CE in excess of $1M for alteration of bed capacity." Table assumes this language pro-

vides for coverage of bed increases and decreases with no 10/10/2 exemption.

ARIZONA: *General*: Arizona has no CON statute. Prior CON law was repealed 03/15/85. It does not have an 1122 program.

ARKANSAS: *General*: Arkansas has a certificate of need program and an 1122 program, apparently with identical coverage. *Hospice*: coverage unclear. *Other outpatient ambulatory care facilities*: Arkansas also covers "clinical health centers, multidisciplinary clinics, specialty clinics."

CALIFORNIA: *General*: California law provides various general exemptions from certificate of need coverage in addition to the categorical exemptions described below, including an exemption for facilities providing prepaid health care, facilities providing certain volumes of free care, etc. California CON scheduled to sunset Jan. 1, 1987. *Other outpatient ambulatory care facilities*: California also subjects to limited regulation "free clinics", "psychology clinics", "chronic dialysis clinics", and "employees' clinics." *CE for other specified purposes/expenditure threshold*: California covers a capital expenditure in any amount for a specialty clinic (surgical, chronic dialysis, or rehabilitation clinic) for expanded outpatient capacity. California also covers capital expenditures in excess of $1,000,000 for other projects for a surgical clinic or rehabilitation clinic and capital expenditures in excess of $1,000,000 for services, equipment or modernization of a specialty clinic (*e.g.*, surgical clinic, chronic dialysis clinic, rehabilitation clinic). *Bed capacity increases*: California covers bed supply increases, and exempts a bed supply increase less than ten percent of licensed bed capacity or ten beds whichever is less in a two-year period for certain classes of health facilities, if certain occupancy rate and accessibility standards are met by the facility. In addition, California exempts up to two additions of five SNF beds for a distinct part SNF of a Primary Health Service hospital if certain occupancy and cost conditions are met. Certain other bed supply increase project exemptions are available under California law. *Bed category changes*: California covers conversion of beds from general acute, general acute rehabilitative, skilled nursing, intermediate care-developmental disabilities, intermediate care-other, acute psychiatric, specialized care, chemical dependency recovery, bed categories to skilled nursing, psychiatric, intermediate care beds to any other category, except that California exempts conversion of a general acute care hospital's distinct part SNF or ICF beds licensed as of March 1, 1983 to other categories provided that the conversion may not exceed during any three-year period five percent of the existing beds in the category to which the conversion is made. California exempts use of beds licensed in one category for another category of use if such changes do not exceed five percent of total bed capacity at any time, except that a facility may use an additional five percent of its beds in this manner if

seasonal fluctuations justify it. *Health service additions*: California covers establishment of specified new special services, *e.g.*, radiation therapy department, burn center, emergency center, psychiatric service, intensive care newborn nursery, cardiac surgery, cardiac catheterization laboratory. California also covers establishment of certain special services by a surgical or rehabilitation clinic. *Acquisition of major medical equipment*: California covers acquisitions of diagnostic or therapeutic equipment by primary care clinics, psychology clinics, and specialty care clinics in excess of $1,000,000. *Construction, development or establishment of new health care facilities*: Establishment of a new primary care clinic (*e.g.* community clinic, free clinic, employees' clinic), psychology clinic, and chronic dialysis clinic are not subject to review. Also exempt are conversion of an existing specialty clinic to a primary care clinic or conversion of a primary care clinic from one licensure category to another. *Other specified projects:* California covers conversion of an entire existing hospital, SNF, or ICF from one licensure catagory to another. California covers conversion of a primary clinic (community, free, employees' clinic) to a specialty clinic (surgical, chronic dialysis, rehabilitation clinic). California covers conversion of a specialty clinic from one category to another. California covers a project by a health facility for expanded outpatient surgical capacity. California covers relocation of a hospital, SNF, ICF, or specialty clinic (surgical clinic, chronic dialysis clinic, rehabilitation clinic) to a different or adjacent site.

COLORADO: *General*: Colorado's CON law underwent minor amendment in 1985. *Kidney disease treatment centers, ambulatory surgery centers, freestanding emergicenters*: The capital and other projects by or on behalf of these facilities which are subject to review are limited to capital expenditures regardless of purpose in excess of the capital expenditure threshold. *Facilities for the provision of outpatient therapy services including speech pathology*: No such projects have been proposed and it is unclear whether they would be subject to review. LF SHPDA 1/84. *Other ambulatory care facilities*: Colorado covers "facilities for the mentally retarded," "habilitation centers for brain-damaged children," and "pilot project rehabilitative nursing facilities." *General purpose CE/expenditure threshold*: Colorado's general purpose capital expenditure threshold covers expenditures in excess of $2,000,000 for "provision of clinically-related health care services" and excludes expenditures for a set of specified non-clinical services. *Capital expenditures for additions of health services/expenditure threshold*: Colorado covers capital expenditures in excess of $1,000,000 to "create or change" health services. *CE for other specified purposes/expenditure threshold*: Colorado covers the replacement of beds exceeding the capital expenditure threshold. *Bed supply increases only, bed category changes and bed relocations*: Colorado covers bed supply increases, category changes, and relocations in excess of twenty beds over

a two-year period. *Other entities, persons, other specified projects*: Colorado covers expenditures for major medical equipment by or on behalf of any person in excess of $1,000,000 to provide "clinically related health care" which includes equipment not located in or providing services to inpatients of a hospital.

CONNECTICUT: *General*: Connecticut amended its CON law in 1985. *Inpatient rehabilitation facilities, ambulatory surgical facilities, organized ambulatory health care facilities*: Coverage unclear. *Other entities, persons*: Connecticut covers "coordination, assessment and monitoring agencies," student/faculty infirmaries, and "homemaker home health aide agencies." *Bed capacity increases and decreases*: Connecticut statute expressly covers only substantial decrease in total bed capacity. Bed supply increases are apparently included under statutory health service/function addition coverage. *Additions of new health services*: Connecticut covers additions of health services or functions, except additions of ambulatory services by HMOs, by all health care facilities or institutions (including state health care facilities or institutions) except home health care agencies, homemaker-home health aide agencies, and coordination, assessment, and monitoring agencies. *Other specified projects*: Connecticut covers transfer of ownership or control of a health care facility or institution (except home health care agencies and homemaker home health aide agencies) prior to initial licensure. Connecticut covers increases in coordination, assessment, and monitoring agency staffing by a specified percentage. Connecticut covers the termination of its Medicaid provider agreement by a nursing home. *Other entities, persons, other specified projects*: Connecticut covers expenditures by any person in excess of $400,000 to acquire "imaging equipment" which will not be owned by or located in a health care facility.

DELAWARE: *General*: Delaware has certificate of need and 1122. Tables show CON coverage. *Other entities*: Delaware covers independent blood banks. *Other specified projects*: Delaware covers pre-development expenditures in excess of $50,000.

DISTRICT OF COLUMBIA: *General*: The D.C. CON law underwent minor amendment in 1985. *Health care facilities subject to review*: The District of Columbia covers health care facilities only if they have an annual operating budget of at least $250,000. *Other entities, persons*: D.C. covers diagnostic health care facilities. *CE for other specified purposes/expenditure threshold*: D.C. covers capital expenditures intended to permit the increase of patient load or units of service by forty percent over present capacity and capital expenditures to permanently close a health care facility. *Additions of new health services/annual operating cost threshold*: D.C. regulations appear to provide for coverage of new health services both regardless of annual operating cost, and if they exceed an annual operating budget. *Other entities, persons, other specified projects*: D.C.

covers acquisition of MME with a fair market value in excess of $400,000 by or on behalf of physicians, dentists, or other individual providers of individual group practice.

FLORIDA: *General*: Florida CON law underwent minor amendment in 1985. Portions of Florida CON law sunset in 1987. *Home health agency*: HHA coverage limited to HHAs certified or seeking certification as a Medicare home health services provider. Project coverage limited to establishment of a new HHA. *Bed capacity increases and decreases*: Florida covers increases in bed supply and any change in the number of psychiatric or rehabilitation beds. *Bed category changes*: Florida covers bed category conversions only between SNF and ICF beds, and only if the conversion exceeds 10/10/2, unless the facility is licensed for both SNF and ICF. *Other specified projects*: Florida covers conversion from one type of health care facility to another and transfer of a CON.

GEORGIA: *General*: The Georgia CON law was amended in 1985. Georgia has CON and 1122. Facilities and projects identified as covered on Tables may be covered under either or both CON and 1122. *Medically-oriented residential care facilities*: Georgia covers only "personal care homes" not in existence on the effective date of the CON statute. *Family planning/abortion centers/clinics*: Only abortion centers covered. *Acquisition of existing facilities*: Reviewable only under the state's 1122 program, except that acquisitions of publicly owned and operated health care facilities subject to CON review. *Bed capacity increases only*: Georgia exempts bed supply increases less than ten beds or ten percent of bed capacity, whichever is less, in any two-year period if the facility occupancy rate in the preceding year is more than eight-five percent. *Other specified projects*: Georgia covers conversion or upgrading of a health care facility not previously subject to review under the CON law to a health care facility subject to review.

HAWAII: *Medically-oriented residential care facilities*: Coverage unknown. *Other outpatient ambulatory care facilities*: Hawaii also covers centers for dental surgery; dental clinics; cosmetic surgery centers; any provider of medical or health services organized as a not-for-profit or business corporation other than a professional corporation; and any provider of medical or health services which describes itself to the public as a "center," "clinic" or by any name other than the name of one or more of the practitioners providing these services. *CE for other specified purposes*: Hawaii covers capital expenditures in excess of $600,000 for acquisition of existing health care facilities. *Termination of a health service*: Hawaii covers terminations but exempts service terminations by a health care facility that is ceasing its entire operation. *Acquisitions of major medical equipment*: Hawaii has a $250,000 threshold for acquisitions of new medical equipment and a $400,000 threshold for replacement of medical equip-

ment. *Other specified projects*: Hawaii covers change of location of a health service. *Other entities, persons, acquisition of MME*: Hawaii covers acquisitions of MME by offices of physicians, dentists, or other practitioners of the healing arts.

IDAHO: *General*: Idaho has an 1122 program, but no CON program. Table displays 1122 coverage. *Other specified projects, CE for other specified purposes*: Idaho covers development of a new facility, and a capital expenditure for development of a new facility, which will result in the addition of new licensed beds.

ILLINOIS: *General*: Portions of the Illinois CON law are scheduled to sunset Jan. 1, 1986. *Addition of new health services/annual operating cost threshold*: Illinois covers additions of the following services if their annual operating costs exceed the threshold: blood bank; diagnostic imaging; emergency services; laboratory; occupational therapy; outpatient ambulatory care; pharmacy; physical therapy; respiratory therapy; and surgery. Additions of the following services are covered regardless of cost: acute mental illness; alcoholism treatment; burn treatment; cardiac catheterization; computer systems; end stage renal disease; intensive care; medical-surgical; non-hospital based ambulatory surgery; obstetrical services; open heart surgery; pediatric services; perinatal-high risk; radiation therapy; rehabilitation services. *Other specified projects*: Illinois covers discontinuation of a health care facility.

INDIANA: *General*: Indiana's CON law was amended in 1985. Indiana CON law sunsets June 30, 1987. *Skilled nursing facilities and intermediate care facilities*: Indiana exempts CE by or on behalf of health care facilities for SNF/ICF beds which are not certified to participate in Medicare or Medicaid. *Kidney disease treatment centers (including freestanding hemodialysis units)*: Indiana does not cover freestanding hemodialysis units. *CE for changes in bed category*: Indiana covers changes in health care facility bed category from any category to certified long-term care SNF/ICF beds. Indiana covers changes in Medicaid-certified hospital or SNF/ICF beds to Medicaid-reimburseable ICF/mentally-retarded beds. *Other specified projects*: Indiana covers the application of a SNF or ICF for certification to participate in Medicare or Medicaid.

IOWA: *General*: Iowa has CON and 1122. Entities and projects identified as covered in Tables may be covered under either 1122 or CON or both. *Freestanding emergicenter; birthing center; public health center, outpatient physical therapy center*: The state CON statute provides for coverage of "organized outpatient health facilities," (defined as "a facility, not part of a hospital, organized and operated to provide health care to noninstitutionalized and non-homebound persons on an outpatient basis; it does not include private offices or clinics of individual physicians, dentists, or other practitioners, or groups of practitioners who are health care

providers''). State regulations have defined this to include, but not be limited to, ''family planning clinics, neighborhood health centers, community mental health centers, drug abuse or alcoholism treatment centers, and rehabilitation facilities.'' According to the SHPDA, whether or not emergicenters, birthing centers, public health centers, and outpatient physical therapy centers would be covered would depend upon the proposed facilities' relationship to a hospital, if any; the services to be provided by the facility and whether such services constitute ''health care''; and the facilities' characteristic as a private office or clinic of a practitioner or a group of practitioners. LF SHPDA 2/84. *Bed capacity increases and decreases*: CON statute and regulations could be read not to cover. LF SHPDA 2/84 indicates state does review permanent changes in bed capacity whether the changes result in the addition or deletion of beds. 1122 coverage parallels CON coverage under ''election not to review'' regulation. *Other specified projects*: Iowa covers relocation of a health care facility, relocation of one or more health services from one physical facility to another. *Other entities, persons, other specified projects*: Iowa covers expenditure by or on behalf of individual health care provider or group of providers in excess of $400,000 for MME to be installed in a private office or clinic.

KANSAS: *General*: The Kansas CON statute sunsetted July 1, 1985. Kansas has a statutory moratorium on new hospital construction and additions or relocations of hospital beds through July 1, 1986.

KENTUCKY: *General*: Kentucky has CON and 1122. Facilities and projects identified in Tables may be covered under either or both programs. *Public health centers*: Kentucky covers capital expenditures in excess of the threshold by county and district health departments and establishment by such departments of health services for which there are separate licensure categories, *e.g.* primary care centers or home health agencies. CON not required to establish traditional ''public health'' services. LF SHPDA 2/84. *Addition of a new health service/annual operating cost threshold*: Kentucky covers health service additions exceeding an AOC threshold and also covers additions of health services subject to licensure or for which there is a component of the SHP without regard to annual operating costs. The services in the SHP are: acute care services; open heart surgery, cardiac catheterization, radiation therapy which utilizes mega-voltage equipment, ESRD services, CT scanners, NMR, long-term care services. *Acquisitions of existing facilities*: Acquisitions of hospitals, SNFs, ICFs, kidney disease treatment center including freestanding hemodialysis units, and ambulatory surgical facilities subject to 1122 review only if associated with capital expenditure in excess of $100,000. LF SHPDA 2/84. *Other specified projects*: Kentucky requires CON to alter the geographic service area which has been designated on a certificate of need or license, and to transfer a CON for establishment of a new facility or replacement of an existing facility.

LOUISIANA: *General*: Louisiana has a Section 1122 program. Although it does not have a certificate of need law, it does have a statutory program of new home health agency licensure requiring a determination of need for the new home health agency by the designated planning agency. *Home health agency*: Louisiana's home health agency coverage is limited to establishment and licensure of new HHA. *Other specified projects*: Louisiana covers relocation of a previously approved and licensed facility within the same service area.

MAINE: *General*: Maine CON law was amended in 1985. Maine has CON and 1122. It elects not to review under 1122 projects not reviewed under CON. *CE for other specified purpose*: Maine covers a capital expenditure in excess of $350,000 for purchase or other acquisition of a health care facility. *Bed capacity increases and decreases*: Maine covers increases and decreases in licensed bed capacity by more than five beds or ten percent, whichever is less, in any two-year period. *Bed category change*: Maine covers increases or decreases in the number of beds licensed in particular levels of care by more than five beds or ten percent, whichever is less, in any two-year period. *Bed relocations*: Maine covers relocations of bed by more than five beds or ten percent of bed capacity, whichever is less, in any two-year period. *Additions of new health services/annual operating cost threshold*: Maine covers additions of health services with annual operating costs in excess of the threshold. It also covers the addition of any new health service (except an organized outpatient facility) without regard to cost. It also covers addition of the following services if the proposed addition duplicates a service presently offered in the proponent's service area: alcohol rehabilitation (inpatient or outpatient); medical-surgical (adult) (where converted from psychiatric beds); rehabilitation (inpatient or outpatient); and speech pathology. *Other entities, other specified projects*: Maine regulations provide for coverage of the acquisition by any person of NMR scanning equipment that is to be used to provide services to persons other than hospital inpatients.

MARYLAND: *General*: Maryland exempts certain projects to close all or part of a hospital. Maryland's CON law was amended in 1985. *General purpose CE*: Maryland exempts CE for site acquisitions, acquisitions of business or office equipment not directly related to patient care and CE to the extent they are directly related to acquisition and installation of MME. Maryland also exempts certain CE made as part of a health facility merger, consolidation, or conversion to non-health related use. It covers CE for predevelopment activities. *CE for other specified purpose*: Maryland covers capital expenditures which result in any increase or decrease in the volume of one patient service where over a two-year period the change is twenty-five percent or more of that volume. Maryland covers CE that result in a substantial change in the bed capacity of a health care facility. *Bed capacity increases and decreases*: Maryland exempts cer-

tain bed capacity changes undertaken pursuant to a health facility merger, consolidation, or conversion to non-health related use. *Addition of new health service*: Maryland exempts additions of new health services with annual operating revenue exceeding the threshold if such revenue is entirely associated with the use of medical equipment. *Acquisition of MME*: Maryland has a program of licensure of major medical equipment in excess of $600,000 used to provide health services acquired, leased, operated, or received by any person. The program uses review criteria and standards similar to those used under CON, but is separate from the state's CON program. *Construction, development, or other establishment of new health care facilities*: Maryland covers establishment of new health care facilities, relocation of an existing health care facility to a new site, and complete replacement of an existing facility on the same, contiguous, or adjacent site. *Other specified projects*: Maryland covers the addition of an HHA branch office by an existing HHA or home health service, establishment of an HHA or home health service in a new location by an existing HHA, or transfer of ownership of an HHA branch office or service. Maryland covers changes in the number of kidney dialysis stations of a health care facility. Maryland covers any increase or decrease in magnitude of any single patient service over a two-year period, other than change in bed capacity, by which the facility plans to change the volume of the service by twenty-five percent or more. For determination of percentage of planned change, the volume of service shall be that unit which is normally measured for the service, and shall be for the last prior annual recording period used by the facility. Certain services volume changes undertaken pursuant to facility merger, consolidation, or conversion to non-health related uses are exempted.

MASSACHUSETTS: *Freestanding emergicenters*: "Clinic" definition in Mass. regulations appears to include emergicenters and bring them within CON. *Other entities*: Massachusetts covers institutions for care of unwed mothers and clinical laboratories. *Bed capacity increases only*: Massachusetts exempts one-time increases of four beds or a series of increases in bed capacity up to four beds, except in intensive care, coronary care, neo-natal intensive care, or renal dialysis beds and so long as the capital expenditure required for the increase or increases does not exceed $150,000. *Addition of health services/annual operating cost threshold*: Massachusetts covers the addition of major services (*e.g.*, any service in the acute services, chronic rehabilitation, and mental health services categories, and establishment of a satellite clinic or unit of a facility) without regard to annual operating cost. Other service additions are covered if they exceed an annual operating threshold of $250,000. *Acquisitions of existing facilities*: Massachusetts regulations indicate that acquisition of an existing health care facility by another health care facility is covered as a substantial change in services of the acquiring facility.

In addition, transfers of ownership of a health care facility require a finding of need for the facility at the proposed location by the state department of health. *Other specified projects*: Conversion of an entire facility from one licensure category to another is covered.

MICHIGAN: *General*: Michigan has CON and 1122. Facilities and projects identified in Tables may be covered under either or both programs. *Home health agencies*: State CON statute provides that HHAs will be covered once HHAs are licensed in the state. *Other entities*: Michigan covers clinical laboratories. *Bed category changes*: Michigan covers bed category changes that result in an increase or decrease in beds in an obstetrical department, long-term care unit or psychiatric unit.

MINNESOTA: *General*: Minnesota does not have a certificate of need law. State law places a moratorium on all new hospital construction and construction or modification by or on behalf of a hospital that increases bed capacity, relocates beds from one physical facility or to another, or otherwise results in an increase or redistribution of bed capacity, with certain exceptions through June 30, 1987. Minnesota has an 1122 program, and elects not to review or non-substantively reviews most projects.

MISSISSIPPI: *General*: Mississippi CON law amended in 1985. Mississippi CON scheduled to sunset July 1, 1986. *Bed capacity increases, CE for bed capacity increases, CE for bed category changes, CE for bed relocations*: Bed-related coverage after 1985 amendments unclear. The statute covers bed relocations of more than ten beds or ten percent over a two-year period specified by the state agency with a CE below $150,000, bed conversions "of the total bed capacity of a designated licensed category or sub-category of any health care facility" with a similar 10/10/2 and a CE below $150,000, and alteration, refurbishing, or modernizing of a unit or department where such beds are located with a CE under $150,000. Not clear if the foregoing transactions would be covered when associated with a CE *exceeding* $150,000. Additionally, bed capacity additions not clearly covered, although legislative intent to cover them is apparent in statutory moratorium on CONs, which exempts certain bed additions. *Other specified projects*: Mississippi covers relocation of a health care facility, or portion thereof, or major medical equipment, or relocation of a health care service from one site to another. Mississippi covers acquisition of MME exceeding threshold by any person.

MISSOURI: *Health maintenance organizations*: Missouri law and regulations do not provide an HMO exemption. *CE for bed category change*: Missouri exempts nursing facility conversion of beds from practical to professional levels of care if the facility meets the professional level licensure requirements. *Additions of new health services*: Missouri exempts additions of home health services. *Other specified projects*: Missouri covers pre-development expenditures exceeding $150,000.

MONTANA: *General*: Montana CON law sunsets July 1, 1987. The Montana CON statute underwent minor amendment in 1985. *Other entities*: Montana covers infirmaries, *e.g.*, facilities located in a university, college, government institution, or industry for the treatment of the sick and injured on an inpatient or outpatient basis. Montana also covers adult day care centers. *Other specified projects*: Montana covers expansion of the geographic service area of a home health agency. *Other entities, persons, other specified projects*: Montana covers acquisition by any person of MME in excess of the threshold provided such an acquisition would require a CON if undertaken by or on behalf of a health care facility.

NEBRASKA: *General*: Nebraska has 1122 and CON. It elects not to review under 1122 projects not reviewable under CON. *Addition of new health services/annual operating cost threshold*: Nebraska covers additions of new home health services regardless of annual operating cost and additions of other services in excess of the threshold. *Acquisition of existing facility*: Various types of acquisitions of facilities and ownership interests in facilities are covered.

NEVADA: *General*: Nevada statute amended 1985. *Other entitites*: Nevada covers any facility providing health services which is entitled to receive reimbursement from any public agency as a health facility. *Other entities, other specified projects*: Nevada covers any facility which acquires medical equipment with a cost exceeding the MME threshold. *CE for other specified purpose*: Nevada covers CE in excess of $100,000 for expansion or consolidation of a health service. *Other specified projects*: Nevada covers expansion or consolidation of health services exceeding $297,500 annual operating expenses. Nevada covers conversion of an existing office of a health practitioner to a health facility if the establishment of the offices would have exceeded the $100,000 CE or $297,500 annual operating cost threshold.

NEW HAMPSHIRE: *General*: New Hampshire CON law was amended in 1985. *Other entities*: New Hampshire covers independent diagnostic laboratories as health care facilities. New Hampshire covers "mental retardation facilities." *Bed capacity increases, bed category changes*: New Hampshire covers increases in bed capacity or changes in bed category exceeding ten beds or ten percent, whichever is less, in a five-year period. *Addition of new services*: New Hampshire covers addition of "special inpatient services," including but not limited to alcohol and drug dependency, psychiatric services, and physical rehabilitation. *Acquisition of existing facilities*: New Hampshire covers transfers of ownership of health care facilities except where the transfer would be subject to the provisions of revaluation of assets as outlined in the Federal Deficit Reduction Act of 1984. *Other entities, persons, other specified projects*: New Hampshire covers acquisitions of diagnostic or therapeutic equipment in excess of a $400,000 threshold by or on behalf of any health care provider.

NEW JERSEY: *General*: New Jersey has both CON and 1122. Projects and facilities identified in Tables may be covered under either or both programs. *Kidney disease treatment centers, ambulatory surgery centers, organized ambulatory health care facilities, other ambulatory care facilities*: New Jersey covers public health centers, diagnostic centers, treatment centers, rehabilitation centers, outpatient clinics and dispensaries. The identity of these facilities is not further defined in law or regulations. The Tables assume kidney disease treatment centers, ambulatory surgery centers, and organized ambulatory health care facilities are included within these terms. *Other entities*: New Jersey covers certain bio-analytical laboratories. *CE for other specified purpose*: New Jersey covers capital expenditures in excess of $150,000 for facility/service planning and any capital expenditure which will result in a bed capacity decrease. *Additions of new health services*: New Jersey regulations contain a comprehensive list of new health services categories subject to review and components thereof which are not subject to review as new services. *Construction, development, or other establishment of new health care facility*: In addition to coverage of construction, development, or establishment of a new health care facility, New Jersey expressly covers replacement of an existing bed-related health care facility, establishment of a bed-related satellite location for an existing health care facility, relocation and replacement of an existing non-bed-related health care facility into a new health service area or to an area that results in problems of access to populations historically served by the facility, and establishment of a non-bed satellite service of an existing health care facility into a new health service area. *Acquisition of existing facilities*: Acquisition of facilities and of varying types and degrees of ownership interests in health care facilities are covered. *Other specified projects*: New Jersey covers transfer of a patient care service in whole or in part to another corporate entity; addition of regionalized services identified in Dept. of Health planning regulations; addition of renal dialysis stations; and addition of operating rooms.

NEW MEXICO: *General*: New Mexico has 1122, not CON.

NEW YORK: *Home health agencies*: Coverage limited to "public and voluntary" HHAs. *Ambulatory surgery centers and organized ambulatory health care facilities*: New York covers diagnostic centers, treatment centers, rehabilitation centers. ASC and various types of OAHCFS would appear to be covered under these categories, if they meet organizational and other criteria for distinguishing such centers from the private practice of medicine. *Acquisition of major medical equipment*: New York covers addition or replacement of any equipment regardless of cost utilized in the provision of therapeutic radiology, open heart surgery, cardiac catheterization, kidney and heart transplant, acute or chronic renal dialysis, CT scanners, burn care, and extra corporeal shockwave lithotripters that will significantly increase the capacity of providing such service. *Other specified*

projects: New York covers a change in the method of delivery of a licensed service regardless of cost. New York covers addition or deletion of approval to operate part-time clinics. New York covers any proposal involving a total project cost exceeding $10,000 or an increase in operating costs by a medical facility that has been determined to be inappropriate or for which there has been a determination of no public need and which is identified as unneeded in the state medical facilities plan.

NORTH CAROLINA: *General*: North Carolina's statute was amended in 1985. *Hospices, other entities, CE for other specified purposes, other specified projects*: North Carolina covers local health departments, but only to the extent of covering their CE in excess of the expenditure threshold. North Carolina covers construction, development, or establishment of a hospice if the operating budget exceeds $100,000 or if there is a CE in excess of the expenditure minimum by or in behalf of the hospice. No other hospice or local health department projects are covered. *CE for bed capacity increases and decreases*: North Carolina covers CE in any amount for bed supply increases and CE in excess of the expenditure minimum ($1,000,000) for bed supply decreases. *CE for changes in bed category*: North Carolina covers CE for bed category changes only if they involve a CE in excess of the expenditure minimum. *Other specified projects*: Conversion of non-health care facility beds to health care facility beds is covered. *Other entities, other specified projects*: North Carolina covers acquisition by any person of "major medical equipment" that includes magnetic resonance imaging or lithotripters, regardless of ownership or location.

NORTH DAKOTA: *General*: North Dakota's statute was amended in 1985. *Home health agency*: HHA coverage limited to expedited review of establishment of new HHA or expansion of geographic area of service of existing HHA. *General purpose CE*: Capital expenditures for site acquisition are exempt. *CE for service additions*: North Dakota statute defines "capital expenditure" in such a way as to incorporate the expenditure threshold into the definition. Not clear if coverage of capital expenditures for service additions intended to include the threshold. Table assumes it does not.

OHIO: *General*: The Ohio CON statute was amended in 1985. *CE for changes in bed category*: Ohio covers any redistribution of beds by service associated with a capital expenditure in any amount and amounting to nine beds or ten percent of bed capacity, whichever is less, in a two-year period. *CE for other specified purpose*: Ohio covers CE for decrease in bed capacity of more than nine beds or ten percent of bed capacity, whichever is less, within a two-year period. *Bed category changes*: Ohio covers redistribution of beds by service involving beds registered as psychiatric, physical rehabilitation, alcohol rehabilitation, or long-term care.

Bed relocation: Ohio covers bed relocations from one physical facility or site to another excluding relocation within a health care facility or among buildings of a facility at the same location. *Addition of a new health service*: Ohio covers initiation of any program of heart, lung, liver, or pancreas transplant, without regard to cost. Other health services covered if they exceed annual operating cost threshold. *Acquisitions of MME*: Ohio has $200,000 threshold for acquisition of technologically innovative medical equipment; $400,000 for all other major medical equipment. *Other specified projects*: Ohio covers change from one category of health facility to another.

OKLAHOMA: *General*: Oklahoma has CON and 1122. Tables show CON coverage. Not known if 1122 program coverage different. Portions of the Oklahoma CON law to sunset in 1989. *Other entities*: Oklahoma covers such institutions or services operated by the federal government in the state as may be authorized by the U.S. Congress. *CE regardless of purpose/expenditure threshold*: The expenditure threshold for SNF/ICF, and medically-oriented residential care facilities is $150,000; for hospitals and all other health care facilities it is $600,000. *CE for bed supply increases and decreases, relocations and category changes*: Oklahoma covers only SNF/ICF and medically-oriented residential care facilities under these forms of coverage. *Bed capacity increases and decreases, category changes and relocations*: These forms of coverage apply to health care facilities other than ICF, SNF, medically-oriented residential care facilities. *Construction, development, or other establishment of new health care facility*: Regulations cover. However, current statute could be read narrowly to cover only for SNF, ICF, medically-oriented residential care facility.

OREGON: *General*: Oregon's statute was amended in 1985. *Other entities*: Oregon covers college infirmaries. *General purpose CE/expenditure minimum*: Oregon covers expenditures for clinically-related services in excess of the lesser of $1,000,000 or $250,000 plus .5% of the gross revenues for the last fiscal year. Site acquisitions are exempt. *CE for other specified purposes*: Oregon covers non-clinically related capital expenditures in excess of the general purpose CE threshold. *Additions of health services*: Home health services, residential care or treatment of the elderly and residential or outpatient services for alcoholism, drug abuse, or mental or emotional disturbances are exempt. Oregon covers additions of all other health services which could significantly add to the cost of patient care or compromise quality of care. With several exceptions, Oregon regulations define new services with annual operating expenses exceeding $340,000 as significantly adding to patient care costs. *Other entities, other specified projects*: Oregon covers acquisition of MME exceeding a $1 million threshold by any person.

PENNSYLVANIA: *CE for bed category changes*: Pennsylvania exempts bed category changes within levels of care in a nursing home.

RHODE ISLAND: *Other outpatient ambulatory care facilities*: Rhode Island's coverage of organized ambulatory health care facilities includes central service facilities, treatment centers, diagnostic centers, outpatient clinics, and health centers. *Other entities*: Rhode Island covers clinical laboratories. *Addition of a health service*: Rhode Island statute provides for coverage of addition of any health service proposed to be offered to patients or the public by a health care facility which meets criteria defined in state agency rules and regulations. As of December 1985, service additions associated with a $75,000 annual operating cost and service expansions associated with a $150,000 increase in operating expenditures were covered. *Other specified projects*: Rhode Island covers major expansion of an existing program which increases operating expenditures in a health care facility by $150,000 in one year. *Other entities, persons, other specified projects*: Rhode Island covers acquisition of new health care equipment proposed to be utilized by a health care provider (whether practicing alone or as a member of a partnership, corporation, organization, or association) costing in excess of $150,000.

SOUTH CAROLINA: *General*: Project coverage shown is under South Carolina's CON program. Not known if 1122 coverage differs significantly. *Other entities*: South Carolina covers "outpatient facilities," not further specified or defined. South Carolina covers state health laboratories and nurse's training facilities.

SOUTH DAKOTA: *General purpose CE*: South Dakota has a $183,690 threshold for nursing facilities, $670,404 for all other health care facilities. *CE for other specified purposes*: South Dakota covers capital expenditures which decrease licensed bed capacity by ten beds or ten percent, whichever is less, in any two-year period. *Bed category changes*: South Dakota covers permanent changes in bed category in excess of five beds per calendar year. *Additions of health services*: South Dakota covers nursing home service additions with annual operating costs in excess of $91,845; other health facility service additions in excess of $279,336. *Acquisitions of major medical equipment*: South Dakota has a $400,000 threshold for MME in a hospital or physician's office; $150,000 in a nursing care facility.

TENNESSEE: *General*: The Tennessee CON law was amended in 1985. Portions of the Tennessee CON statute sunset June 30, 1991. *Bed capacity increases and decreases*: Nursing homes may increase or decrease licensed bed supply by ten beds or ten percent, whichever is less, in any two-year period. *Bed category changes*: Tennessee covers bed category changes between acute care and long-term care beds only. *Additions of health services, terminations of health services*: Tennessee covers additions and terminations of a specified set of major health care services, regardless of cost (e.g., (1) medical; (2) surgical; (3) obstetrical; (4) psychiatric/retardation/substance abuse treatment—adult, adolescent, children, and youth;

(5) special care units—ICU, CCU, burn, cardiac catheterization, neonatal nursery; (6) open heart surgery; (7) therapeutic radiology; (8) all outpatient services; (9) pediatric; (10) total body and head CT scanners; (11) home health services; (12) ambulatory primary care clinic services; (13) ambulatory surgery; (14) magnetic resonance imaging; (15) extracorporeal shock wave lithotripsy; (16) any service established and staffed as an organized unit with a projected annual operating budget in excess of $500,000; and (17) any service enumerated above provided to a facility or institution on a mobile basis). *Other specified projects*: Tennessee covers resumption of operation of any facilities or services previously discontinued (for reasons other than temporary closure for construction purposes) for one year or more. Tennessee covers change in site of a health care facility other than a primary care center or public health department. *Other entities*: Tennessee covers persons or combinations of persons engaged in a joint or cooperative enterprise designed to provide central facilities and/or services to two or more health care facilities. *General purpose CE, Acquisition of MME*: Tennessee exempts CE and acquisition of MME not directly related to patient care.

TEXAS: *General*: Texas does not have a CON or 1122 program. Current Texas law authorizes the Governor to establish a capital expenditure review program such as section 1122 if necessary to prevent "loss of federal funds."

UTAH: *General*: Utah does not have a CON or 1122 program.

VERMONT: *Medically-oriented residential care facilities*: Vermont covers community care homes having or seeking a CON to acquire a licensed capacity in excess of fifteen beds. *Organized outpatient health care facilities*: Vermont covers facilities or institutions which offer ambulatory care to two or more persons. *Other entities*: Vermont covers independent diagnostic laboratories. *Bed increases, category changes, relocations*: Vermont covers increases, category changes, relocations exceeding four beds or ten percent of capacity, whichever is less in a four-year period.

VIRGINIA: *General*: The Virginia CON statute was amended in 1985. Virginia exempts nursing homes affiliated with nonprofit life care communities not participating in Medicaid. *Inpatient rehabilitation facilities*: Coverage unclear. *Other entities*: Virginia covers specialized centers or clinics developed for the purpose of providing radiation therapy, CT scanning, or other medical or surgical treatments requiring the utilization of equipment not usually associated with the provision of primary health services. *Addition of new health services*: Home health service additions are exempt. *Other persons, entities, other specified projects*: Virginia covers acquisition by or on behalf of a physician's office of medical equipment exceeding $400,000 generally and customarily associated with provision of health services in an inpatient setting.

WASHINGTON: *CE for additions, terminations of health services*: Washington covers CE for substantial change in services, defined as any capital expenditure for addition or termination of the following services: alcohol/substance abuse; burn unit; cardiac catheterization; chronic renal dialysis; kidney lithotripty; CT-computed tomography; NMR-nuclear magnetic resonance; PET-positron emission tomography; emergency services including regular outpatient emergency services staffed by physicians at a health care facility, and the provision of ambulance services, including licensed air ambulance services; inpatient psychiatric services; neonatal special care - level III; obstetrics - level I; obstetrics - level II; obstetrics - level III; open heart surgery; pediatrics - level I; pediatrics - level II; pediatrics - level III; radiation therapy-megavoltage, orthovoltage; rehabilitation - level I; rehabilitation - level II; rehabilitation - level III; change in the number of dialysis stations in a health care facility; and change from mobile to fixed base CT scanning. In addition, Washington covers as substantial changes in services the introduction of a new technology for diagnosis or treatment, a "change in the level of service," and the offering of any services at a new location not formerly part of the health care facility's campus. *Acquisitions of existing facilities*: Washington covers sale, purchase, or lease of part or all of any hospital.

WEST VIRGINIA: *General*: West Virginia CON statute amended in 1985. West Virginia has CON and 1122. Tables show CON coverage. Not known if 1122 coverage is different. *Organized ambulatory health care facilities*: West Virginia covers "ambulatory health care facilities," *e.g.*, freestanding outpatient facilities not including physicians or other health professionals' offices. *Other entities*: West Virginia covers inpatient "community mental health centers" (*e.g.*, private facilities providing comprehensive services and continuity of care as emergency, outpatient, partial hospitalization, inpatient, and consultation and education for individuals with mental illness, mental retardation, or drug or alcohol addiction). *CE for other specified purposes*: West Virginia covers any capital expenditure associated with the partial or total closure of a health care facility. West Virginia also covers capital expenditures in excess of $1,000,000 for acquisitions of an existing health care facility. *Other specified projects*: West Virginia covers a substantial change in bed capacity if the change is associated with and within two years of a previous CE for which a CON was issued. West Virginia covers a substantial change, defined by regulations, in an institutional health service for which a CON is in effect. *Other persons, entities, other specified projects*: West Virginia covers acquisition of major medical equipment exceeding $400,000 by any person.

WISCONSIN: *General*: Wisconsin statute amended 1985. Wisconsin CON law sunsets July 1, 1989. *General purpose CE; acquisition of major medical equipment*: Wisconsin covers all-purpose hospital CEs and clinical medical equipment acquisitions exceeding $1,000,000 and the same transactions

for nursing home health care facilities exceeding $600,000. However, the threshold for hospital CEs to renovate part or all of a hospital or to convert to a new use is $1,500,000. *Bed capacity increases*: Wisconsin covers bed capacity increases by hospitals and nursing homes, and additions of psychiatric or chemical dependency beds by any person. *Addition of new health services*: Wisconsin covers addition of organ transplantation program, burn center, neonatal ICU, cardiac program, and transport services. *Acquisition of existing facilities*: Wisconsin covers acquisitions of hospitals only. *Other specified projects*: Wisconsin covers construction or total replacement of a nursing home and construction or operation of an ambulatory surgical facility or home health agency. *Other entities, other specified projects*: Wisconsin covers obligations of an expenditure exceeding $1,000,000 by or on behalf of an independent practitioner, partnership, unincorporated medical group, or service corporation for clinical medical equipment.

WYOMING: *General*: The Wyoming CON law was amended in 1985. The Wyoming CON law sunsets July 1, 1989. *Other entities*: Wyoming covers "providers of alternative health care" (not otherwise defined). *Acquisition of MME*: Expenditure threshold for acquisition of MME by SNF/ICF is $150,000. Expenditure threshold for acquisition of MME by all other health care facilities is $400,000. *Other specified projects*: Wyoming covers acquisition of MME exceeding threshold by licensed practitioners' offices.

TABLE 1: STATE PARTICIPATION IN CERTIFICATE OF NEED AND SECTION 1122 REVIEW PROGRAMS

State	Year First CON Statute Adopted	Year CON Statute Repealed or Scheduled to Sunset	Year Current Section 1122 Agreement Entered Into
Alabama	1977		
Alaska	1976		
Arizona	1971	1985	
Arkansas	1975		1973
California	1969	1987	
Colorado	1973		
Connecticut	1969		
Delaware	1978		1973
Dist. of Columbia	1964		
Florida	1972	1987*	
Georgia	1974		1974
Hawaii	1974		
Idaho	1980	1983	1983
Illinois	1974		
Indiana	1980	1985	1973

TABLE 1: Continued

State	Year First CON Statute Adopted	Year CON Statute Repealed or Scheduled to Sunset	Year Current Section 1122 Agreement Entered Into
Iowa	1977		1973
Kansas	1972	1985	
Kentucky	1972		1974
Louisiana			1973
Maine	1978		1973
Maryland	1968		
Massachusetts	1971		
Michigan	1972		1973
Minnesota	1971	1984	1974
Mississippi	1979	1986	
Missouri	1979		
Montana	1975	1987	
Nebraska	1979		1973
Nevada	1971		
New Hampshire	1979		
New Jersey	1971		1974
New Mexico	1978	1983	1973
New York	1964		
North Carolina	1978		
North Dakota	1971		
Ohio	1975		
Oklahoma	1971	1989*	1974
Oregon	1971		
Pennsylvania	1979		
Rhode Island	1968		
South Carolina	1971		
South Dakota	1972		
Tennessee	1973	1991*	
Texas	1975	1985	
Utah	1979	1984	
Vermont	1979		
Virginia	1973		
Washington	1971		
West Virginia	1977		1974
Wisconsin	1977	1989	
Wyoming	1977	1989	

*Only some portions of the statute are scheduled to sunset.

SOURCES: CONGRESSIONAL BUDGET OFFICE, HEALTH PLANNING: ISSUES FOR REAUTHORIZATION 14-15 (1982); Author's survey of state statutes and communications with state health planning and development agencies, 1985.

TABLE 2: HEALTH CARE FACILITIES, ETC., SUBJECT TO STATE CON/1122 REVIEW

(See attached notes for explanatory information, definitions, and state-by-state comments. The symbol "N" in the table below indicates that additional information is provided in the state-by-state comments.)

	Ala	Ak	Ariz[N]	Ark[N]	Cal[N]	Colo	Conn	Del[N]	DC[N]	Fla[N]
Hospitals	X	X		X	X	X	X	X	X	X
Skilled Nursing Facilities	X	X		X	X	X	X	X	X	X
Intermediate Care Facilities	X	X		X	X	X	X	X	X	X
Medically-Oriented Residential Care Facilities				X		X	X			
Inpatient Rehabilitation Facilities	X[N]			X	X	X	N		X	
Home Health Agencies	X			X			X	X	X	X[N]
Hospices				N		X			X	X
Kidney Disease Treatment Centers (Including Freestanding Hemodialysis Units)	X	X		X		X[N]	N	X	X	X
Health Maintenance Organization (Subject to Exemption)	X			X	X	X		X	X	X
Ambulatory Surgery Centers	X	X		X	X	X[N]	N	X	X	X
All Organized Ambulatory Health Care Facilities/ Outpatient Clinics				X			N	X	X	
Specified Ambulatory Health Care Facilities, i.e.:										
Freestanding Emergicenters									X	X
Ambulatory Obstetrical Facilities/Birthing Centers										
Family Planning/ Abortion Centers/ Clinics				X						
Community Health Centers/Clinics				X	X	X				
Public Health Centers	X			X						
Community Mental Health Centers	X			X		X		X	X	
Facilities for Provision of Outpatient Therapy Services Including Speech Pathology				X		N				
Outpatient Rehabilitation Facility	X[N]			X	X	X		X		
Other Outpatient Ambulatory Care Facilities				N	X[N]	X[N]	X[N]			
Other Entitites, Persons	X[N]	X[N]				X[N]	X[N]	X[N]	X[N]	

	Ga[N]	Haw	Id[N]	Ill	Ind[N]	Ia[N]	Ks[N]	Ky[N]	La	Me[N]
Hospitals	X	X	X	X	X	X		X	X	X
Skilled Nursing Facilities	X	X	X	X	X[N]	X		X	X	X
Intermediate Care Facilities	X	X	X	X	X[N]	X		X	X	X
Medically-Oriented Residential Care Facilities	X[N]	N		X		X		X		
Inpatient Rehabilitation Facilities	X	X		X	X			X	X	X
Home Health Agencies	X	X						X	X[N]	X
Hospices		X						X		
Kidney Disease Treatment Centers (Including Freestanding Hemodialysis Units)	X	X	X	X	X[N]	X		X	X	X
Health Maintenance Organizations (Subject to Exemption)	X	X		X		X				X
Ambulatory Surgery Centers	X	X	X	X		X		X	X	X
Organized Ambulatory Health Care Facilities/ Outpatient Clinics		X				X		X		
Specified Ambulatory Health Care Facilities, i.e.:										
Freestanding Emergicenters		X				N		X		
Ambulatory Obstetrical Facilities/Birthing Centers	X	X				N		X		
Family Planning/ Abortion Centers/ Clinics	X[N]	X				X		X		
Community Health Centers/Clinics		X				X		X		
Public Health Centers		X				N		X[N]		
Community Mental Health Centers		X				X		X		
Facilities for Provision of Outpatient Therapy Services Including Speech Pathology		X				N		X		
Outpatient Rehabilitation Facility		X				X		X		
Other Outpatient Ambulatory Care Facility		X[N]								
Other Entities		X[N]				X[N]		X[N]		X

	Md[N]	Mass	Mich[N]	Minn[N]	Miss[N]	Mo	Mont[N]	Neb[N]	Nev[N]	NH[N]
Hospitals	X	X	X		X	X	X	X	X	X
Skilled Nursing Facilities	X	X	X		X	X	X	X	X	X
Intermediate Care Facilities	X	X	X		X	X	X	X	X	X
Medically-Oriented Residential Care Facilities	X	X	X				X			
Inpatient Rehabilitation Facilities	X	X			X		X	X	X	X
Home Health Agencies	X		X[N]		X		X	X	X	X
Hospices	X		X				X		—	
Kidney Disease Treatment Centers (Including Freestanding Hemodialysis Units)	X	X	X		X	X	X	X	X	X
Health Maintenance Organizations (Subject to Exemption)	X	X	X		X	X[N]	X	X		X
Ambulatory Surgery Centers	X	X	X		X	X	X	X	X	X
All Organized Ambulatory Health Care Facilities/ Outpatient Clinics		X	X				X			
Specified Ambulatory Health Care Facilities, i.e.:										
Freestanding Emergicenters		X[N]					X			
Ambulatory Obstetrical Facilities/Birthing Centers		X	X				X			
Family Planning/ Abortion Centers/ Clinics		X	X				X			
Community Health Centers/Clinics		X	X				X			
Public Health Centers		X	X				X			
Community Mental Health Centers		X	X				X			X
Facilities for Provision of Outpatient Therapy Services Including Speech Pathology		X	X				X			
Outpatient Rehabilitation Facility		X	X				X			
Other Outpatient Ambulatory Care Facility										
Other Entities		X[N]	X[N]				X[N]		X[N]	X[N]

	NJ[N]	NM[N]	NY	NC[N]	ND[N]	Oh[N]	Ok[N]	Or[N]	Pa	RI
Hospitals	X	X	X	X	X	X	X	X	X	X
Skilled Nursing Facilities	X	X	X	X	X	X	X	X	X	X
Intermediate Care Facilities	X	X	X	X	X	X	X	X	X	X
Medically-Oriented Residential Care Facilities	X		X				X		X	
Inpatient Rehabilitation Facilities	X		X	X	X	X	X	X	X	X
Home Health Agencies	X		X[N]	X	X[N]	X				X
Hospices			X	X[N]						X
Kidney Disease Treatment Centers (Including Freestanding Hemodialysis Units)	X[N]	X	X	X	X	X	X	X	X	X
Health Maintenance Organizations (Subject to Exemption)	X			X	X	X	X	X	X	X
Ambulatory Surgery Centers	X[N]	X	X[N]	X	X	X	X	X	X	X
All Organized Ambulatory Health Care Facilities/ Outpatient Clinics	X[N]		X[N]							X
Specified Ambulatory Health Care Facilities, i.e.:										
Freestanding Emergicenters							X			X
Ambulatory Obstetrical Facilities/Birthing Centers								X	X	
Family Planning/ Abortion Centers/ Clinics										
Communith Health Centers/Clinics										X
Public Health Centers	X		X				X			
Community Mental Health Centers							X			X
Facilities for Provision of Outpatient Therapy Services Including Speech Pathology										
Outpatient Rehabilitation Facility	X									X
Other Outpatient Ambulatory Care Facility										X[N]
Other Entities	X[N]			X[N]			X[N]	X[N]		X[N]

	SC	SD	Tn[N]	Tx[N]	Ut[N]	Vt	Va[N]	Wa	WV[N]	Wi[N]	Wy[N]
Hospitals	X	X	X			X	X	X	X	X	X
Skilled Nursing Facilities	X	X	X			X	X	X	X	X	X
Intermediate Care Facilities	X	X	X			X	X	X	X	X	X
Medically-Oriented Residential Care Facilities		X				X[N]					X
Inpatient Rehabilitation Facilities	X	X	X					X	X	X	X
Home Health Agencies	X	X	X			X		X	X	X	
Hospices							X	X			
Kidney Disease Treatment Centers (Including Freestanding Hemodialysis Units)	X	X				X	X	X	X	X	X
Health Maintenance Organization (Subject to Exemption)	X	X	X			X	X	X	X		
Ambulatory Surgery Centers	X	X	X			X	X	X	X	X	X
All Organized Ambulatory Health Care Facilities/ Outpatient Clinics			X			X[N]			X[N]		
Specified Ambulatory Health Care Facilities, i.e.:											
Freestanding Emergicenters			X								
Ambulatory Obstetrical Facilities/Birthing Centers											
Family Planning/ Abortion Centers/ Clinics			X								
Community Health Centers/Clinics			X								
Public Health Centers	X	X									
Community Mental Health Centers	X					X			X		
Facilities for Provision of Outpatient Therapy Services Including Speech Pathology						X					
Outpatient Rehabilitation Facility											
Other Outpatient Ambulatory Care Facility											
Other Entities	X[N]		X[N]			X[N]	X[N]		X[N]	X[N]	X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Ala	Ak	Ariz[N]	Ark[N]	Cal[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $736,200			X $736,200	
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold		X[N] $1,000,000		X	
CE for Bed Capacity Increases Only/Expenditure Threshold					
CE for Changes in Bed Category/Expenditure Threshold				X	
CE for Bed Relocations/ Expenditure Threshold				X	
CE for Additions of Health Services/Expenditure Threshold		X $1,000,000		X	
CE for Terminations of Health Services/ Expenditure Threshold		X $1,000,000		X	
CE for Other Specified Purpose/Expenditure Threshold	X[N] $245,000				X[N] $1,000,000
PROJECT COVERAGE					
Bed Capacity Increases and Decreases	X				
Bed Capacity Increases Only					X[N]
Bed Category Changes	X				X[N]
Bed Relocations	X				
Additions of New Health Services/Annual Operating Costs Threshold	X[N]			X $306,705	X[N]
Terminations of a Service					
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $245,000			X $400,000	X[N] $1,000,000
Construction, Development or Other Establishment of New Health Care Facilities	X	X $1,000,000			X[N]
Acquisitions of Existing Facilities					
Other Specified Projects	X[N]				X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Colo	Conn	Del[N]	DC[N]	Fla[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X[N] $2,000,000	X $714,000	X $150,000	X $600,000	X $736,200
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold				X	
CE for Bed Capacity Increases Only/Expenditure Threshold					
CE for Changes in Bed Category/Expenditure Threshold				X*	
CE for Bed Relocations/ Expenditure Threshold				X*	
CE for Additions of Health Services/Expenditure Threshold	X[N] $1,000,000		X	X	
CE for Terminations of Health Services/ Expenditure Threshold				X	X
CE for Other Specified Purpose/Expenditure Threshold	X[N] $2,000,000			X[N]	
PROJECT COVERAGE					
Bed Capacity Increases and Decreases		N			X[N]
Bed Capacity Increases Only	X[N]		X*		
Bed Category Changes	X[N]		X*		X[N]
Bed Relocations	X[N]		X*		
Additions of New Health Services/Annual Operating Costs Threshold		X[N]	X	X[N] X[N] $250,000	X $306,750
Terminations of a Service		X			
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $1,000,000	X $400,000	X $150,000	X $400,000	X $400,000
Construction, Development or Other Establishment of New Health Care Facilities	X		X	X	X
Acquisition of Existing Facilities				X	
Other Specified Projects	X[N]	X[N]	X[N]	X[N]	X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Ga[N]	Haw	Id[N]	Ill	Ind[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $736,200	X $600,000	X $600,000	X $736,200	X $750,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold					
CE For Bed Capacity Increases Only/Expenditure Threshold			X		X
CE for Changes in Bed Category/Expenditure Threshold			X		X[N]
CE for Bed Relocations/ Expenditure Threshold					
CE for Additions of Health Services/Expenditure Threshold			X $250,000		
CE for Terminations of Health Services/ Expenditure Threshold					
CE for Other Specified Purpose/Expenditure Threshold		X[N] $600,000	X[N]		
PROJECT COVERAGE					
Bed Capacity Increases and Decreases		X		X*	
Bed Capacity Increases Only	X[N]		X		
Bed Category Changes		X		X*	
Bed Relocations		X		X*	
Additions of New Health Services/Annual Operating Costs Threshold	X	X	X	X[N], X[N] $306,750	
Terminations of a Service		X[N]		X	
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $429,012	X[N] $250,000/ $400,000		X $400,000	X $750,000
Construction, Development or Other Establishment of New Health Care Facilities	X				
Acquisitions of Existing Facilities	X[N]				
Other Specified Projects	X[N]	X[N]	X[N]	X[N]	X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Ia^N	Ks^N	Ky^N	La	Me^N
CAPITAL EXPENDITURE COVERARE					
General Purpose CE/ Expenditure Threshold	X $600,000		X $603,600	X $600,000	X $350,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold				X*	
CE for Bed Capacity Increases Only/Expenditure Threshold					
CE for Changes in Bed Category/Expenditure Threshold				X	
CE for Bed Relocations/ Expenditure Threshold					
CE for Additions of Health Services/Expenditure Threshold	X $250,000			X	X
CE for Terminations of Health Services/ Expenditure Threshold				X	X
CE for Other Specified Purpose/ Expenditure Threshold					X^N $350,000
PROJECT COVERAGE					
Bed Capacity Increases and Decreases	X^N		X		X^N
Bed Capacity Increases Only					
Bed Category Changes	X		X		X^N
Bed Relocations	X		X		X^N
Additions of New Health Services/Annual Operating Costs Threshold			X^N; X^N $251,500		X^N; X^N $145,000
Terminations of a Service	X		X		
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X^N $400,000		X $402,000		X $300,000
Construction, Development or Other Establishment of New Health Care Facilities	X		X		X
Acquisitions of Existing Facilities			X^N	X	
Other Specified Projects	X^N		X^N	X^N	X^N

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Md[N]	Mass	Mich[N]	Minn[N]	Miss[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X[N] $730,000	X $600,000	X $150,000		X $1,000,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold					
CE for Bed Capacity Increases Only/Expenditure Threshold					N
CE for Changes in Bed Category/Expenditure Threshold					X[N]
CE for Bed Relocations/ Expenditure Threshold					X[N]
CE for Additions of Health Services/Expenditure Threshold					X
CE for Terminations of Health Services/ Expenditure Threshold					
CE for Other Specified Purpose/Expenditure Threshold	X[N]				
PROJECT COVERAGE					
Bed Capacity Increases and Decreases	X*[N]				
Bed Capacity Increases Only		X[N]	X		N
Bed Category Changes			X[N]		
Bed Relocations					
Additions of New Health Services/Annual Operating Costs Threshold	X[N] $305,000	X[N],X[N] $250,000	X		X $150,000
Terminations of a Service	X				
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	N	X $400,000			X $750,000
Construction, Development or Other Establishment of New Health Care Facilities	X[N]		X		X
Acquisitions of Existing Facilities		X			
Other Specified Projects	X[N]	X[N]			X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Mo	Mont[N]	Neb[N]	Nev[N]	NH[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $736,000	X $750,000	X $512,100	X $714,000	X $1,000,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold			X*		
CE for Bed Capacity Increases Only/Expenditure Threshold	X* $736,000				
CE for Changes in Bed Category/Expenditure Threshold	X*[N] $736,000		X*		
CE for Bed Relocations/ Expenditure Threshold	X* $736,000		X*		
CE for Additions of Health Services/Expenditure Threshold			X	X $100,000	
CE for Terminations of Health Services/ Expenditure Threshold			X		
CE for Other Specified Purpose/Expenditure Threshold				X[N] $100,000	
PROJECT COVERAGE					
Bed Capacity Increases and Decreases		X*			
Bed Capacity Increases Only				X*	X[N]
Bed Category Changes		X*			X[N]
Bed Relocations		X*			
Additions of New Health Services/Annual Operating Costs Threshold	X[N] $306,000	X $100,000	X[N], X $256,050	X $297,500	X[N]
Terminations of a Service					
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $400,000	X $500,000	X $400,000	X $400,000	X
Construction, Development or Other Establishment of New Health Care Facilities	X $736,000	X	X		
Acquisitions of Existing Facilities			X[N]		X[N]
Other Specified Projects	X[N]	X[N]		X[N]	X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	NJ[N]	NM[N]	NY	NC[N]	ND[N]
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $600,000	X $600,000	X $300,000	X $1,000,000	X[N] $750,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold		X		X[N] $1,000,000	
CE for Bed Capacity Increases Only/Expenditure Threshold					
CE for Changes in Bed Category/Expenditure Threshold				X[N]	
CE for Bed Relocations/ Expenditure Threshold				X	
CE for Additions of Health Services/Expenditure Threshold		X		X	X[N]
CE for Terminations of Health Services/ Expenditure Threshold		X		X	
CE for Other Specified Purpose/Expenditure Threshold	X[N]			X[N]	
PROJECT COVERAGE					
Bed Capacity Increases and Decreases	X		X		
Bed Capacity Increases Only					
Bed Category Changes	X		X		
Bed Relocations	X		X		
Additions of New Health Services/Annual Operating Costs Threshold	X[N]		X	X $306,750	X $300,000
Terminations of a Service	X		X		
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $400,000		X[N]	X $600,000	X $500,000
Construction, Development or Other Establishment of New Health Care Facilities	X[N]		X	X	
Acquisitions of Existing Facilities	X[N]				
Other Specified Projects	X[N]		X[N]	X[N]	

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Oh	Ok[N]	Or	Pa	RI
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $714,000	X[N] $600,000/ $150,000	X[N] $1,000,000	X $736,200	X $150,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold		X[N]			
CE for Bed Capacity Increases Only/Expenditure Threshold				X*	X*
CE for Changes in Bed Category/Expenditure Threshold	X[N]	X[N]		X*[N]	X*
CE for Bed Relocations/ Expenditure Threshold		X[N]		X*	X*
CE for Additions of Health Services/Expenditure Threshold				X	X
CE for Terminations of Health Services/ Expenditure Thresholds	X				
CE for Other Specified Purpose/Expenditure Threshold	X[N]				
PROJECT COVERAGE					
Bed Capacity Increases and Decreases		X[N]			
Bed Capacity Increases Only	X		X*	X*	
Bed Category Changes	X[N]	X[N]			
Bed Relocations	X[N]	X[N]	X		
Additions of New Health Services/Annual Operating Costs Threshold	X[N],X[N] $297,500	X $250,000	X[N] $340,000	X $306,750	X[N] $75,000/ $150,000
Terminations of a Service					
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X[N] $400,000/ $200,000	X $400,000	X $1,000,000	X $400,000	X[N] $150,000
Construction, Development or Other Establishment of New Health Care Facilities	X	X	X	X	X
Acquisitions of Existing Facilities		X			
Other Specified Projects	X[N]		X[N]		X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	SC	SD	Tn^N	Tx^N	Ut^N
CAPITAL EXPENDITURE COVERAGE					
General Purpose CE/ Expenditure Threshold	X $600,000	X^N $670,404/ $183,690	X^N $1,000,000		
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold					
CE for Bed Capacity Increases Only/Expenditure Threshold					
CE for Changes in Bed Category/Expenditure Threshold					
CE for Bed Relocations/ Expenditure Threshold					
CE for Additions of Health Services/Expenditure Threshold	X	X			
CE for Terminations of Health Services/ Expenditure Thresholds		X			
CE for Other Specified Purpose/Expenditure Threshold		X^N			
PROJECT COVERAGE					
Bed Capacity Increases and Decreases			X^N		
Bed Capacity Increases Only	X	X			
Bed Category Changes	X	X^N	X^N		
Bed Relocations			X		
Additions of New Health Services/Annual Operating Costs Threshold	X $250,000	X^N $279,336/ $91,845	X^N,X^N $500,000		
Terminations of a Service	X		X^N		
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $400,000	X^N $400,000/ $150,000	X $1,000,000		
Construction, Development or Other Establishment of New Health Care Facilities	X		X		
Acquisitions of Existing Facilities	X				
Other Specified Projects			X^N		

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Vt	Va[N]	Wa	WV[N]
CAPITAL EXPENDITURE COVERAGE				
General Purpose CE/ Expenditure Threshold	X $150,000	X $600,000	X $1,071,000	X $714,000
CE For Bed Capacity Increases and Decreases/ Expenditure Threshold				X*
CE for Bed Capacity Increases Only/Expenditure Threshold		X		
CE for Changes in Bed Category/Expenditure Threshold				X*
CE for Bed Relocations/ Expenditure Threshold		X*		X*
CE for Additions of Health Services/Expenditure Threshold			X[N]	X
CE for Terminations of Health Services/ Expenditure Threshold			X[N]	X
CE for Other Specified Purpose/Expenditure Threshold				X[N]
PROJECT COVERAGE				
Bed Capacity Increases and Decreases				
Bed Capacity Increases Only	X[N]		X	
Bed Category Changes	X[N]		X	
Bed Relocations	X[N]			
Additions of New Health Services/Annual Operating Costs Threshold	X	X[N]	X $536,000	X $297,500
Terminations of a Service				
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X $125,000	X $400,000	X $1,071,000	X $400,000
Construction, Development or Other Establishment of New Health Care Facilities	X		X	X
Acquisitions of Existing Facilities			X[N]	
Other Specified Projects		X[N]		X[N]

TABLE 3: CAPITAL AND OTHER PROJECTS BY OR ON BEHALF OF HEALTH CARE FACILITIES, ETC. SUBJECT TO STATE CON/1122 REVIEW

	Wi^N	Wy^N
CAPITAL EXPENDITURE COVERAGE		
General Purpose CE/ Expenditure Threshold	X^N $1,000,000/ $600,000	X $714,000
CE for Bed Capacity Increases and Decreases/ Expenditure Threshold		X*
CE for Bed Capacity Increases Only/Expenditure Threshold		
CE for Changes in Bed Category/Expenditure Threshold		
CE for Bed Relocations/ Expenditure Threshold		
CE for Additions of Health Services/Expenditure Threshold		
CE for Terminations of Health Services/ Expenditure Threshold		X
CE for Other Specified Purpose/Expenditure Threshold		
PROJECT COVERAGE		
Bed Capacity Increases and Decreases		
Bed Capacity Increases Only	X^N	
Bed Category Changes		
Bed Relocations		
Additions of New Health Services/Annual Operating Costs Threshold	X^N	X $150,000
Terminations of a Service		
Acquisitions of Major Medical Equipment/ Equipment Expenditure Threshold	X^N $1,000,000/ $600,000	X^N $400,000/ $150,000
Construction, Development or Other Establishment of New Health Care Facilities		X
Acquisitions of Existing Facilities	X^N	
Other Specified Projects	X^N	X^N

Reform Revisited: A Review of the Indiana Medical Malpractice Act Ten Years Later

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I. Introduction

In the mid-1970's, both the private and public sectors nationwide became alarmed at the significant costs associated with malpractice liability in the health professions.[1] Indiana, one of the first states to seek a legislative solution to the perceived problem of increasing costs, enacted the Indiana Medical Malpractice Act[2] (Act) in 1975. However, a nationwide reassessment of the malpractice controversy has been triggered in the mid-1980's by the recurrence of a marked increase in malpractice claims against physicians and hospitals and by reports of drastic increases in the cost of liability insurance. The direction of current solutions to the malpractice controversy is decidedly different from earlier reforms.

In the 1980's, the focus of legislative solutions is not on wholesale tort law reform. Rather, the activity is directed toward reassessing the reforms made in the 1970's with a goal of making additional reforms to respond to the economic realities of the 1980's. The conflicting forces of plaintiffs seeking larger recoveries and defendants attempting to limit recovery make medical malpractice litigation an obvious area for continued efforts for legislative reform.

It is important that legislators and lobbyists reflect on the history of the reforms of the 1970's before considering what changes are appropriate in the 1980's. Although evaluations of the success of earlier medical malpractice reforms must be subjective, an objective assessment of the impact of the reforms can be made. This Article will review the reform in medical malpractice litigation in Indiana by considering the

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[1] *See, e.g.*, Nat'l Center for Health Statistics, Dep't of Health, Education, & Welfare, Medical Malpractice Closed Claim Study 1976 (1978); Nat'l Center for Health Statistics, Dep't of Health, Education & Welfare, Medical Malpractice Closed Claim Study 1970 (1973).

[2] Ind. Code §§ 16-9.5-1-1 to -10-5 (1982).

original purpose of the Act, the functioning of the medical review panel established by the Indiana statute, constitutional challenges to the Indiana statute, and the effect of changes in federal law on state malpractice reforms.

II. The Purposes and Goals of the Indiana Act

The Indiana Medical Malpractice Act was passed in response to an outcry over drastic increases in malpractice insurance premiums for health professionals.[3] The legislature believed that these increased costs, along with the unavailability of insurance for some health professionals, caused health care providers to discontinue services, thereby reducing the health care services available to the public.[4] The Act was intended to protect the public from decreased services by protecting health care providers from the cancellation of insurance coverage.[5]

While there has been no agreement among commentators as to the cause of the increased premiums,[6] to date at least thirty states have enacted legislation attempting to resolve this perceived crisis.[7] In an effort to balance the interest of the private plaintiff with the public's interest in preserving the health care industry, the legislative solution in Indiana was twofold. The Act provides for (a) limiting the amount of damages and attorney's fees that a plaintiff can recover and (b) a process of screening malpractice claims by a medical review panel.[8]

The effectiveness of the Act and how well the solution has worked

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[3]LaCava, *A Legislative Response: The Indiana Experience*, 3 Health Span 14, 14 (1986).

[4]Rohrabaugh v. Wagoner, 274 Ind. 661, 667, 413 N.E.2d 891, 894 (1980); Johnson v. St. Vincent Hosp., 273 Ind. 374, 387, 404 N.E.2d 585, 594 (1980).

[5]*Id.*

[6]Some authors suggest the rise in cost was due to a widespread reaction to one company's poor investments. *See* Neubauer & Henke, *Medical Malpractice Legislation: Laws Based on a False Premise*, Trial, Jan. 1985, at 64, 65. Others reason that an increase in the size and frequency of claims led to the rise in premiums. *See* Sloan, *State Responses to the Malpractice Insurance "Crisis" of the 1970s: An Empirical Assessment*, 9 J. of Health Pol. Pol'y & L. 629 (1985).

[7]It is difficult to determine the exact number of states enacting such legislation because several states are in the process of revising, enacting, or revoking their legislation. A state by state statutory review is beyond the scope of this article. However, it is clear that Indiana is not alone in attempting to remedy the medical malpractice crisis. *See generally* Klein, *A Practical Assessment of Arizona's Medical Malpractice Screening System*, 1984 Ariz. St. L.J. 335, 343. For examples of comparative legislation in other states, see Ariz. Rev. Stat. Ann. §§ 12-561 to -569 (1982 & Supp. 1985); Md. Cts. & Jud. Proc. Code Ann. §§ 3-2A-01 to -09 (1984 & Supp. 1985); Mass. Gen. Laws Ann., ch. 231, § 60B (West 1985 & Supp. 1986).

[8]Ind. Code §§ 16-9.5-1-1 to -10-5 (1982).

have been subject to considerable debate.[9] Panels, in theory, handle claims more quickly with lower costs than trial litigation.[10] Moreover, they encourage settlement of meritorious claims while discouraging baseless claims.[11] Critics, however, point out that panel review adds another layer of proceedings, is likely to involve substantial legal expenses, and may encourage the filing of claims by providing an informal, initially less expensive proceeding.[12] While the use of a panel has not been proven to encourage settlement, to resolve cases more quickly, or to reduce the size of awards or number of lawsuits filed,[13] a panel may serve other purposes. It can be a tool for early trial preparation, and because the opinion of the panel is nonconclusive evidence at a subsequent trial,[14] use of the panel may encourage thorough preparation of evidence early in litigation.

The impact of the Indiana Act on medical malpractice litigation has been more dramatic than merely a change in procedure, however. The changes appear to reflect an attitudinal change toward the purpose of tort law. It may no longer be the sole purpose of tort resolution in the medical malpractice area simply to compensate the victim for damages and deter harmful behavior. There now seems to be a legislatively-recognized goal of promoting the economy and protecting the health care industry. Compensation for harm resulting from deviation from the standard of care required of a doctor now seems to be tempered by an economically motivated leveler.

It is beyond the scope of this Article to speculate whether this legislative action simply replaces historical societal limitations. In the past, close, lifelong doctor-patient relationships functioned to restrain patients from filing medical malpractice claims. In today's more impersonal society, such lawsuits are no longer taboo. Also, the ability of a community to process information about the competence of a doctor no longer seems sufficient to "weed out" or control less competent doctors. To insure that all victims of medical malpractice can recover in today's more litigious atmosphere, the Act limits the amount of damages and attorney's fees recoverable by the plaintiff and provides for panel review of malpractice claims before lawsuits are filed.[15]

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[9]*See* LaCava, *supra* note 3.

[10]*See* Sloan, *supra* note 6.

[11]*See* LaCava, *supra* note 3, at 16.

[12]*See* Sloan, *supra* note 6, at 636.

[13]*Cf.* Daughtrey & Smith, *Judges' Views of Medical Malpractice Review Panels*, VA. B.A.J., Spring 1985, at 14; Klein, *supra* note 7.

[14]IND. CODE § 16-9.5-9-9 (1982).

[15]*See id.* §§ 16-9.5-1-1 to -10-5.

III. Functioning of the Act

A. How Medical Panels Work—The Statutory Scheme

Essentially, the Indiana Act calls for a specific timetable. Before the plaintiff may file any action in court, he must first file a proposed complaint with the Indiana Department of Insurance.[16] Upon receipt of the proposed complaint, the Department of Insurance will, within ten days, forward a copy to each health care provider named as a defendant.[17] After twenty days from the filing of the proposed complaint with the Department of Insurance, either party may serve on the Commissioner of Insurance by registered or certified mail a request for the formation of a medical review panel.[18]

Within fifteen days of filing this request, the parties should select a chairperson by agreement.[19] If they cannot agree on the selection, the Act states that,

> either party may request the clerk of the supreme court to draw at random a list of five (5) names of attorneys qualified to practice and presently on the rolls of the supreme court and maintaining offices in the county of venue designated in the proposed complaint or in a contiguous county.[20]

The party making such a request is required to pay a fee.[21] Beginning with the plaintiff, each side then has five days to strike a name from the list. If a party does not strike a name, the opposing side may request in writing that the clerk strike for the party, and the clerk must strike.[22] Striking continues until one name remains. Within five days after the last name remains, the clerk must notify that person and the parties of the name of the selected chairperson.[23] The chairperson then must either send a written acknowledgment of his appointment to the clerk within fifteen days, or if he does not want to serve, he must show that service would constitute an unreasonable burden or undue hardship.[24]

After the chairperson is selected, the parties must select the other panel members.[25] Within fifteen days after the chairperson is selected,

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[16] *Id.* §§ 16-9.5-9-1, -2.
[17] *Id.*
[18] *Id.*
[19] *Id.* § 16-9.5-9-3(a).
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *Id.* § 16-9.5-9-3(a), (c).
[25] *Id.* § 16-9.5-9-3(b)(1)-(2).

each side chooses one health care provider to serve on the panel. Within fifteen days of their selection, these two providers then select a third provider for the panel.[26] If the two providers do not choose a third panelist, the chairperson selects the third provider.[27]

Challenges without cause may be made to any selection within ten days after selection of that panel member.[28] If two such challenges are made, the chairperson within ten days proposes a special list of three qualified panelists.[29] Each side then has ten days to strike one of the three, with the party whose appointment was challenged striking last.[30] When the final member is named, the chairperson should, within five days, notify the Commissioner of Insurance and the parties of the names and addresses of panel members and the date on which the last member was selected.[31] The panel is then required to render its expert opinion within 180 days after the selection of the last member.[32]

The entire panel review process should take nine months.[33] However, the reality is much different from the mechanism set out in the Act.

B. How Medical Panels Work—Reality

The nine-month statutory timetable is rarely, if ever, met. One reason is that the large number of complaints filed has caused delays. The number of complaints filed has skyrocketed since the Act was passed. In 1975, the year of enactment, only one complaint was filed, but 773 complaints were filed with the Commissioner in 1985.[34] As of December 31, 1985, 4,225 complaints had been filed; of those, only 1,171 were closed.[35] An average complaint took 23.4 months to go through the process as of May 31, 1983.[36] These delays are not simply the fault of "the system;" delays can also be caused by the actions of the parties and of the chairperson, as well as by outside circumstances.

The parties themselves cause delays when the parties do not follow the statutory procedures for panel review. For example, delays arise

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[26]*Id.* § 16-9.5-9-3(b)(2).

[27]*Id.*

[28]*Id.* § 16-9.5-9-3(b)(3).

[29]*Id.*

[30]*Id.*

[31]*Id.* § 16-9.5-9-3(b)(4).

[32]*Id.* § 16-9.5-9-3.5.

[33]*See id.* § 16-9.5-9-3.

[34]*See* PATIENTS COMPENSATION DIV., IND. DEP'T OF INS., YEAR END REPORT AND ACTUARIAL STUDY (1985) [hereinafter YEAR END REPORT].

[35]*Id.*

[36]Cha v. Warnick, 476 N.E.2d 109, 112 (Ind. 1985), *cert. denied*, 106 S. Ct. 249 (1985); *see also* Williams, *Indiana Medical Malpractice Act—The Developing Law*, 27 RES GESTAE 494, 497 (1984).

when the complaint is improperly filed by the plaintiff.[37] In addition, the parties rarely request the formation of the panel as quickly as the Act allows.[38] Further delays occur because the parties rarely invoke the procedure under the authority of the clerk of the supreme court to select a chairperson.[39] Moreover, the nominations of the health care providers are often not made in fifteen days.[40] And finally, delays by the parties in submitting evidence also contribute to the time lag.[41]

The chairperson of the panel also has a significant impact on the flow of the case regardless of the actions of the parties. Novice chairpersons may take a considerable amount of time to become familiar with the Act and may fail to be aware of statutory deadlines or to apply those deadlines strictly.[42]

Delays can also occur after the panel is convened. For example, there can be delays in receiving evidence. Although all evidence submitted to the panel must be in written form, the Act provides that after submission of all evidence, either party may convene the panel in order to question panel members at a time and place agreeable to the panelists.[43] Because the panelists may have other responsibilities, significant delays can occur in finding a time and place agreeable to them.[44]

Further delays may be created when either of the parties or the Insurance Commissioner calls into play the provisions of Chapter 10 of the Act. Either party may file a motion in a court having jurisdiction over the subject matter to determine questions of "any affirmative defense or issue of law or fact that may be preliminarily determined under Indiana Rules of Procedure" or to compel discovery.[45] The panel proceedings are then stayed until the court rules on the motion.[46] Court involvement at this point is limited to the matters set out in the statute.[47] Once the court rules on the motion, its jurisdiction ends, and the panel resumes its consideration of the case.[48] The court's jurisdiction is not properly invoked again until a complaint is filed, after the panel issues an opinion.[49]

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[37]A total of 76 claims filed from 1975 through 1985 involved problems with the initial complaint. YEAR END REPORT, *supra* note 34.

[38]Pinkus, *The Role of the Panel Chairman*, 1984 IND. CONTINUING LEGAL EDUC. FORUM ON PRESENTING A CASE BEFORE MEDICAL REVIEW BOARD IV-1, IV-7.

[39]*Id.*

[40]*Id.*

[41]*Id.*

[42]*Id.*

[43]IND. CODE § 16-9.5-9-5 (1982).

[44]*See supra* notes 37 to 43 and accompanying text.

[45]IND. CODE § 16-9.5-10-1 (1982).

[46]*Id.* § 16-9.5-10-4.

[47]*Id.* § 16-9.5-10-2.

[48]*Id.* §§ 16-9.5-10-1 to -4.

[49]*See* Johnson v. Methodist Hosp. of Gary, 547 F. Supp. 780, 782 (N.D. Ind. 1982).

Some of these delays can be discouraged by the use of judicially-imposed sanctions, for example, fines against the delaying parties or judicial reprimands. Although the Act does not contain specific sanctions for a party's failure to comply with its provisions, the Act does state:

> A party, attorney or panelist who fails to act as required by this chapter without good cause shown is subject to mandate or appropriate sanctions upon application to the court designated in the proposed complaint as having jurisdiction.[50]

Under Chapter 10 of the Act, a party may make a motion for sanctions, but the procedure for the court's ruling on such a motion can create its own problems. A judicial decision on a motion made under Chapter 10 is to be rendered within thirty days after the matter is heard.[51] If there is no hearing, the decision must be rendered within thirty days after the last written response to the motion is filed.[52] However, the Act does not provide explicit sanctions for the failure of a judge to render a decision within the prescribed time. At least one Indiana court has concluded that this time limitation and its purpose are similar to those provided for other civil actions under Indiana Trial Rule 53.1(A).[53] The court of appeals has held that the appropriate sanction for a judge who fails to rule on a Chapter 10 motion within the prescribed time period is disqualification under trial rule 53.1.[54] Perhaps other analogies as to appropriate sanctions could be persuasively made.

C. Statute of Limitations

In addition to the procedural structure of the Act, another important provision is the time limitation for bringing a medical malpractice action. The Act provides:

> No claim, whether in contract or tort, may be brought against a health care provider based upon professional services or health care rendered or that should have been rendered unless filed within two (2) years from the date of the alleged act, omission, or neglect, except that a minor under the full age of six (6) years shall have until his eighth birthday in which to file.[55]

This period is triggered by the occurrence of the act, omission or neglect, *not* by the discovery that the cause of the injury was a health care

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[50]IND. CODE § 16-9.5-9-3.5(b) (1982).
[51]IND. CODE § 16-9.5-10-3.
[52]*Id.*
[53]Hepp v. Pierce, 460 N.E.2d 186, 189 (Ind. Ct. App. 1984).
[54]*Id.*
[55]IND. CODE § 16-9.5-3-1 (1982).

provider's act, omission or neglect.[56] However, where the entire conduct of the doctor constitutes fraudulent concealment, the doctrine of equitable estoppel may prevent a defendant doctor from taking advantage of his deceit by barring the doctor from asserting the statute of limitations as a defense.[57] Fraudulent concealment includes both affirmative acts to conceal information and passive failure to disclose information required by the duties of the doctor-patient relationship.[58] Where the concealment is passive, the concealment is considered to end when the doctor-patient relationship ends; at that time the statute of limitations begins to run.[59]

The statute of limitations may also be tolled under a continuing wrong theory. As described in *Frady v. Hedgcock*,[60] "[w]hen an entire course of conduct combines to produce an injury, the conduct may constitute a continuing wrong so as to delay the running of the statute of limitations. . . . Under this theory, the statutory period commences at the end of the continuing wrongful act."[61] In *Frady*, a wrongful death action was brought under the Act against a physician whose patient had died of renal failure, thought to be caused by the allegedly excessive medication prescribed by the physician. The physician last saw the patient for treatment more than one month before her death. A complaint was filed more than two years after the date of her last visit, but less than two years after her death. The court of appeals found that a material issue of fact existed as to whether the doctor's treatment was a continuing wrong as late as the date of death, so as to toll the limitation period until the date of death.[62] The court also made clear that the statute of limitations of the Act could apply to a wrongful death action if malpractice was the basis of the action. The statutory time period for wrongful death actions would be inapplicable in this case.[63] Therefore, wrongful death actions based upon medical malpractice must be filed within two years of the act, omission, or neglect, not within two years of the date of death.[64]

A recent decision by the Indiana Court of Appeals has an uncertain impact on interpretation of the statute of limitations provision. In *Barnes v. A. H. Robins Co.*,[65] the court of appeals adopted a "discovery" rule

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[56]Colbert v. Waitt, 445 N.E.2d 1000, 1002 (Ind. Ct. App. 1982).
[57]*Id.* at 1002-03.
[58]*Id.* at 1003.
[59]*Id.*; Weinstock v. Ott, 444 N.E.2d 1227, 1236 (Ind. Ct. App. 1983).
[60]497 N.E.2d 620 (Ind. Ct. App. 1986).
[61]*Id.* at 622.
[62]*Id.* at 622-23.
[63]*Id.* at 622.
[64]*Id.*
[65]476 N.E.2d 84 (Ind. Ct. App. 1985).

and found that the statute of limitations commenced when the plaintiff knew or should have discovered that an injury was suffered and was caused by a product or act of another, in this case, an intrauterine device.[66] The court limited this rule to situations where "[the] injury to a plaintiff [was] caused by a disease which may have been contracted as a result of protracted exposure to a foreign substance."[67] In *Walters v. Owens-Corning Fiberglass Corp.*,[68] the United States Court of Appeals for the Seventh Circuit held that exposure to asbestos over a twenty-five year period constituted "protracted exposure to a foreign substance" and allowed the tolling of the statute of limitations until the time of discovery, based on *Barnes*.[69] Future malpractice plaintiffs may use these decisions to argue for broader application of such a rule where the statute of limitations has otherwise expired and may succeed in having the discovery rule apply to occurrences of medical malpractice.

D. Scope of the Act

The Indiana statute is extremely restrictive. It does not apply to all defendant-doctors, and it does not cover all occurrences of malpractice. This strictness causes confusion and statute of limitations problems when the plaintiff is trying to decide if his action is subject to panel review under the Act or if he should proceed directly in court.

1. Qualified Health Care Providers.—The Act applies only to health care providers qualified therein.[70] If the health care provider is not included in the coverage of the Act, the Act is inapplicable and the patient must pursue remedies outside the Act.[71] A qualified health care provider is one who files proof of financial responsibility and pays the surcharge provided for in the Act.[72] If the patient files his complaint in a timely fashion with the Department of Insurance, but the defendant is not a qualified provider under the Act, the filing is apparently ineffective for torts statute of limitation purposes. Although the Act provides for tolling the statute of limitations upon filing of a proposed complaint until ninety days after the panel opinion is issued,[73] this provision is inapplicable if the provider is not qualified. The result is that the statute of limitations will continue to run, and if the time is near, as it inevitably is, it may be too late to file a complaint in court.

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[66]*Id.* at 87-88.
[67]*Id.* at 87.
[68]781 F.2d 570 (7th Cir. 1986).
[69]*Id.* at 572.
[70]IND. CODE § 16-9.5-1-5 (1982).
[71]*Id.*
[72]*Id.* § 16-9.5-2-1.
[73]*Id.* § 16-9.5-9-1.

Certainly the reverse is true. Where the defendant health care provider is qualified, the action must proceed under the Act.[74] The plaintiff's proposed complaint must be filed with the Department of Insurance. If the complaint is mistakenly filed in court instead, it may be subject to summary judgment.[75] If the statutory time limit expires after the filing in court but before dismissal of the action, the plaintiff cannot start over and file the complaint with the Department of Insurance.[76] In other words, if the plaintiff files a complaint within the prescribed time limit but in the wrong forum, it may be too late to correct the mistake. This has been held true in one case despite evidence that the plaintiff had been told incorrectly by the Department of Insurance that the health care provider was not qualified, leading the plaintiff to file the action in the wrong forum.[77]

The Department of Insurance works within a limited budget and with limited resources.[78] Beyond the expected human errors that can occur in recordkeeping, the Act contains provisions that complicate matters even more. The Act provides for a 180-day grace period from the termination of insurance coverage and a showing that coverage is being renewed.[79] Because of this grace period, it may be difficult for a plaintiff to determine if a defendant is qualified under the Act. Because of these complications as well as the unfortunate result to the plaintiff if he files a complaint in the wrong forum, plaintiffs are commonly advised to file both with the court and the Department.[80]

2. Situations Covered by the Act.—The Act contains very broad definitions, which make many types of conduct subject to its provisions. "Malpractice" is defined as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider, to a patient."[81] "Health care" is broadly defined as "any act or treatment performed or furnished, or which should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement."[82]

Although, clearly, typical acts of malpractice are covered by the

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[74]*Id.* §§ 16-9.5-1-5, -9-2.

[75]*See* Whitaker v. St. Joseph's Hosp., 415 N.E.2d 737, 742-45 (Ind. Ct. App. 1981).

[76]*Id.*

[77]*Id.*

[78]Clegg, *Insurance Commissioner's Role*, 1984 IND. CONTINUING LEGAL EDUC. FORUM ON PRESENTING A CASE BEFORE MEDICAL REVIEW BOARD II-1, II-7.

[79]IND. CODE § 16-9.5-4-1(e) (1982).

[80]*See* Clegg, *supra* note 78, at II-7; Murphy, *Pitfalls in Medical Malpractice Panel Practice*, 29 RES GESTAE 178, 178 (1985).

[81]IND. CODE § 16-9.5-1-1(h) (1982).

[82]*Id.* § 16-9.5-1-1(i).

Act, a curious line of cases has found less typical occurrences also covered.[83] In *Ogle v. St. John's Hickey Memorial Hospital*,[84] the rape of one patient by another, allegedly caused by negligence on the part of the hospital, was determined to be a tort action subject to the Act.[85] In *Methodist Hospital of Indiana v. Rioux*,[86] the Act was found to apply to a slip-and-fall action of a patient against a hospital.[87] The *Rioux* decision met with disapproval in *Winona Memorial Foundation v. Lomax*,[88] a later, similar case. The *Lomax* court found that the Act did not apply where the fall occurred during a time when the patient was not receiving treatment or care, nor was attended by any hospital employees.[89] The *Lomax* court felt that literal application of the Act to these circumstances would be absurd, contradictory, and not within the intent of the legislature.[90] These conflicting interpretations are unresolved. Certainly factors of each decision should be weighed by plaintiffs in trying to decide where to file and by defendants in deciding whether to challenge a court action in order to obtain panel review.

Another example of the less typical occurrences found to be covered by the Act arose in *Detterline v. Bonaventura*.[91] The court of appeals found that in an action for wrongful commitment to a mental hospital, the claim must be submitted to a medical review panel under the Act.[92] This decision required a broad reading of the statutory definition of "patient" because the plaintiff had never been examined or seen by the defendant doctor. The patient's wife had arranged for the doctors to sign the commitment papers; her action on the patient's behalf created a sufficient relationship to qualify the plaintiff as a patient.[93]

3. Multiple Defendants.—The Act also creates potential problems when multiple defendants are involved. Compliance with the Act is difficult when some of the defendants are qualified health care providers and some are not. The defendants falling under the Act should be named in a complaint filed with the Department of Insurance, but those not

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[83]*See* Ogle v. St. John's Hickey Memorial Hosp., 473 N.E.2d 1055 (Ind. Ct. App. 1985); Detterline v. Bonaventura, 465 N.E.2d 215 (Ind. Ct. App. 1984); Winona Memorial Found. v. Lomax, 465 N.E.2d 731 (Ind. Ct. App. 1984); Methodist Hosp. of Ind. v. Rioux, 438 N.E.2d 315 (Ind. Ct. App. 1982).

[84]473 N.E.2d 1055 (Ind. Ct. App. 1985).

[85]*Id.*

[86]438 N.E.2d 315 (Ind. Ct. App. 1982).

[87]*Id.*

[88]465 N.E.2d 731 (Ind. Ct. App. 1984).

[89]*Id.* at 741-42.

[90]*Id.* at 734-39.

[91]465 N.E.2d 215 (Ind. Ct. App. 1984).

[92]*Id.* at 216.

[93]*Id.* at 219.

covered by the Act will be sued in a court.[94] In this way, the plaintiff can file against all possible defendants before the statute of limitations runs out.[95] The defendants in the court proceeding will probably want to obtain a stay until a panel opinion has been issued.[96] This allows defendants not only additional time, but also the benefit of learning about the case through its development before the panel.[97]

4. Impact of Recent Amendments. — Recent amendments both to the Act and to the Indiana comparative fault statute affect both the amount of damages a plaintiff can recover and a defendant's liability under the Act. Effective September 1, 1985, plaintiffs with claims of $15,000 or less may choose not to proceed before a panel.[98] However, if the plaintiff chooses to go straight to court, he cannot recover more than $15,000.[99] This new provision allows for a quicker, less costly settlement where the amount involved is small. If the plaintiff discovers after the action has begun that the bodily injury is more serious than previously believed and that $15,000 is insufficient compensation, the plaintiff may move that the action be dismissed without prejudice, and upon dismissal, the plaintiff may proceed as usual under the Act.[100] In such a case, the statute of limitations is extended by 180 days.[101] A 1985 amendment to Indiana's comparative fault statute provides that the comparative fault statute does not apply to an action brought under the Medical Malpractice Act.[102] Thus a malpractice plaintiff cannot invoke the provisions of the comparative fault statute, and a malpractice defendant may be able to utilize defenses such as contributory negligence.[103]

E. How to Participate in the Panel: Cautions and Encouragements

In litigating a malpractice case under the Act, parties can take alternative stances based on their feelings about the panel. They may choose to participate as little as possible, or they may choose to use the panel proceedings as an opportunity to prepare for trial. The first alternative cannot be carried too far, however, without creating the threat of sanctions.[104]

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[94]*See supra* notes 70 to 80 and accompanying text.

[95]Shula, *How to Present Defendant's Case to the Medical Review Panel*, 1984 IND. CONTINUING LEGAL EDUC. FORUM ON PRESENTING A CASE BEFORE MEDICAL REVIEW BOARD III-1, III-2.

[96]*Id.* at III-2.

[97]*Id.*

[98]IND. CODE § 16-9.5-9-2.1(a) (Supp. 1985).

[99]*Id.*

[100]*Id.* § 16-9.5-9-2.1(b).

[101]*Id.* § 16-9.5-3-1(b).

[102]*Id.* § 34-4-33-1.

[103]*See id.*

[104]*See supra* notes 50-54 and accompanying text.

The Act also provides that the panel consider the issues as charged in the complaint when determining its opinion.[105] Although the panel members will concentrate on submissions and medical records, not merely the complaint,[106] any complaint filed in court after panel review should duplicate the proposed complaint considered by the panel.[107] If new theories are submitted to a court after the panel opinion is rendered, the defendant has a basis to argue for reconvening the panel and submitting the new claims to the panel.[108] Furthermore, failure to submit all issues and evidence to the panel is likely to insure an unfavorable decision from the panel. Because the panel opinion is admissible at trial as nonconclusive expert evidence,[109] a party who submits little or no data to the panel risks an unfavorable panel opinion that has a significant effect on the fact-finder at trial. Courts from other jurisdictions have held that a nonparticipating party cannot reveal to the jury that no evidence was presented to the panel.[110] The delay and expense incurred at the panel level should be balanced with these results. The degree of nonparticipation may be limited by these considerations.

However, the disadvantage of plunging into full preparation at the panel stage is the risk of revealing too much to opposing parties. The use of affidavits from experts may lead to early deposition of these people, for example. Balancing this threat, however, is the availability of the three panel members to testify as witnesses at trial and of up to three opinions for submission at trial.[111] (The Act appears to allow multiple opinions from the panel.)[112] The purposes of the Act, then, are probably better served by full participation.

Because the panel is not bound by formalities, the parties can encourage the progress of the proceedings. Because the chairperson is the only attorney on the panel,[113] legal issues and submissions should be restricted to that person, who can present them as appropriate to

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[105]IND. CODE § 16-9.5-9-7 (1982).

[106]*See* Shula, *supra* note 95, at III-11.

[107]*Id.* at III-12.

[108]*Id.*

[109]IND. CODE § 16-9.5-9-9 (1982).

[110]*See, e.g.*, Phoenix Gen. Hosp. v. Superior Court, 138 Ariz. 504, 506, 675 P.2d 1323, 1325 (1984) (en banc); Herrera v. Doctor's Hosp., 360 So. 2d 1092, 1096 (Fla. Dist. Ct. App.), *aff'd*, 367 So. 2d 204 (Fla. 1978).

[111]IND. CODE § 16-9.5-9-9 (1982); *see also* Hobbs v. Tierney, 495 N.E.2d 217, 222 (Ind. Ct. App. 1986) (discussion of panel member's competency as an expert witness to testify in malpractice actions).

[112]*See* Kranda v. Houser-Norborg Medical Corp., 419 N.E.2d 1024, 1034 (Ind. Ct. App.) *reh'g denied*, 424 N.E.2d 1064 (Ind. Ct. App. 1981), *appeal dismissed*, 459 U.S. 802 (1982).

[113]IND. CODE § 16-9.5-9-3 (1982). The other panel members are health care providers, although they may evidently be physician-attorneys.

the other members. Direct discussion about legal issues with the medical members of the panel can lead to unnecessary confusion and risks misunderstanding. Also, the parties may find it appropriate to monitor the chairperson's compliance with statutory deadlines, particularly when dealing with an inexperienced chairperson. In addition, parties can control the speed of the formation of the panel through the selection of the chairperson and the other members by prompt contact with the clerk of the court and, subsequently, with the chairperson.

Parties should also recognize that the Department of Insurance acts only as a recordkeeping body.[114] The Commissioner has no control or interest in creation of the panel, compelling discovery, distribution of evidence to panel members, or determination of sanctions on opposing parties.[115] The Department should not be expected to distribute information, and parties should not involve that body unnecessarily.

Parties must submit evidence to the panel in written form only.[116] Commonly, the chairperson will set up a staggered submission schedule beginning with the plaintiff.[117] In addition to medical records, parties may wish to include medical literature, treatises, and letters from experts.[118] The parties may also want to provide the chairperson with briefs on legal issues which the chairperson is then required to explain to the other panel members.[119]

Although no trial or formal hearing occurs, either party can convene the panel at a time and place agreeable to all the panel members and question panel members about any matter relevant to the issues.[120] Aside from the potential for delays in finding a suitable time and place,[121] this provision can be advantageous to the parties. The practical application of this provision is expansive. Some parties make formal records of the meeting hoping to use statements made by panel members to impeach the members at trial if the panel opinion is adverse.[122] Meetings can also be used to discover potential biases and to determine areas of uncertainty. A party may find it appropriate at panel proceedings to guide a chairperson so that arguments are not presented and only the legitimate inquiry allowed by the Act occurs.

The opinion of the panel is no more than an opinion.[123] It is

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[114]*See supra* note 80.
[115]*Id.*
[116]IND. CODE § 16-9.5-9-4 (1982).
[117]*See* Shula, *supra* note 95, at III-9.
[118]IND. CODE § 16-9.5-9-4 (1982).
[119]*Id.*
[120]*Id.* § 16-9.5-9-5.
[121]*See supra* notes 43 to 44 and accompanying text.
[122]Murphy, *supra* note 80, at 179-80; Shula, *supra* note 95, at III-8, n.1.
[123]IND. CODE §§ 16-9.5-9-7, -9 (1982).

considered expert testimony, not a judgment or determination of either legal issues or damages.[124] The panel has the following four statutory options for its opinion:

> (a) The evidence supports the conclusion that the defendant or defendants failed to comply with the appropriate standard of care as charged in the complaint.
>
> (b) The evidence does not support the conclusion that the defendant or defendants failed to meet the applicable standard of care as charged in the complaint.
>
> (c) That there is a material issue of fact, not requiring expert opinion, bearing on liability for consideration by the court or jury.
>
> (d) The conduct complained of was or was not a factor of the resultant damages. If so, whether the plaintiff suffered:
>
> (1) any disability and the extent of duration of the disability, and
>
> (2) any permanent impairment and the percentage of the impairment.[125]

A party who still wishes to go to trial after issuance of the panel opinion must file his complaint in court ninety days following the receipt of the opinion.[126] Even with a favorable panel opinion, a plaintiff may wish to file a complaint in court to avoid statute of limitations problems if a settlement is delayed. A defendant of course must simply wait for the plaintiff's next steps; an opinion favorable to the defendant is no guarantee that the plaintiff will stop pursuing his claim.

IV. Constitutionality

The Indiana Act withstood early constitutional challenges shortly after its enactment.[127] Several years later, in *Warnick v. Cha*,[128] plaintiffs were again unsuccessful in challenging the constitutionality of certain provisions of the Act. The plaintiffs in *Warnick* alleged that the provisions of the Act that require submission of a claim to a medical review panel

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[124]*Id.*

[125]*Id.* § 16-9.5-9-7.

[126]*Id.* § 16-9.5-9-1.

[127]*See* Johnson v. St. Vincent Hosp., 273 Ind. 374, 404 N.E.2d 585 (1980).

[128]No. SD 83-163 (Jasper Super. Ct. Nov. 2, 1983).

before filing a lawsuit in court[129] violated state and federal constitutional rights to trial by jury and access to courts as well as the equal protection and due process clauses of the fourteenth amendment.[130]

Warnick originated with the filing of a complaint for a declaratory judgment seeking to have the Act declared unconstitutional.[131] The plaintiff had previously filed a medical malpractice action against the same defendant that resulted in a default judgment against the defendant.[132] The Indiana Court of Appeals vacated the default judgment and remanded the case for further proceedings.[133] The Indiana Supreme Court denied transfer.[134]

In the subsequent declaratory judgment action, the trial court held the Act unconstitutional on several bases. The court found that the delay caused by mandatory submission of a malpractice claim to a medical review panel violated the right of free access to courts as guaranteed by the constitution of the state of Indiana and the United States Constitution. The court also held that the mandatory submission provisions violated the right to trial by jury as provided by the constitution of the state of Indiana,[135] as well as the equal protection and due process clauses of the fourteenth amendment to the Constitution of the United States.[136]

On direct appeal, the Indiana Supreme Court reversed the trial court and upheld the constitutionality of the Act.[137] The court discussed *Johnson v. St. Vincent Hospital*,[138] the earlier case, stating that it had recognized in *Johnson* the potential for delays created by the Act but found the delay constitutionally permissible.[139] The court stated, "In other words, the mere fact that there is a delay which may be as long as 23.4 months from the time of filing until the time the panel opinion is rendered is not enough to hold Indiana's Malpractice Act unconstitutional."[140] The court recognized that delays to the claimant were an acceptable trade-off in light of the benefits to be derived. Despite the delays, the Act was a reasonable means to achieve the stated compelling state interest in insuring the continuation of medical services within the state and in dealing with the malpractice insurance emergency that threatened the

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[129]IND. CODE §§ 16-9.5-1-1 to -9-10 (1982).
[130]*Warnick*, No. SD 83-163, at 1.
[131]*Id.*
[132]*Id.* at 1-2.
[133]Cha v. Warnick, 455 N.E.2d 1165 (Ind. Ct. App. 1983), *trans. denied.*
[134]*See Cha*, 476 N.E.2d at 109.
[135]*Warnick*, No. SD 83-163, at 7-10.
[136]*Id.* at 10.
[137]*Cha*, 476 N.E.2d at 109.
[138]273 Ind. 374, 404 N.E.2d 585 (1980).
[139]*Cha*, 476 N.E.2d at 112.
[140]*Id.*

availability of these services. Therefore, the Act was not unconstitutional.[141] The lynchpin of the court's analysis of the constitutionality issue was that the plaintiffs failed to show that a medical malpractice insurance emergency no longer existed in the state. Thus, the *Johnson* analysis that the Act was a reasonable means to respond to that emergency still applied.[142]

Warnick seems decisively to foreclose any attack on the constitutionality of the Act based on delays resulting from the medical review panel process. However, other aspects of the panel procedure may be subject to constitutional challenge. *Warnick* seems to suggest, though, that any such challenge, in order to be successful, would have to rest on evidence that invalidates or undermines the legislative judgment underlying the Act.[143]

Interestingly, other provisions of the Act were not challenged in *Warnick*. For example, the provision limiting a plaintiff's recovery to a certain amount was not challenged by the *Warnick* plaintiffs. Indiana remains one of a relatively small number of states that limit the amount of damage awards to plaintiffs in medical malpractice cases.[144]

V. Beyond the Panel

It may never be possible to determine conclusively whether the statutory measures serve the goals for which they were intended. Despite the limitation on recovery and despite the effect of panels in discouraging lawsuits and encouraging settlements, some costs remain unaffected. Both parties can suffer large degrees of non-monetary cost, including the psychological and emotional strain of adversarial actions. The Act makes the goal of compensating victims for damages secondary to that of assuring that insurance companies can reliably and predictably insure doctors. The long-term effect is that health care providers are encouraged to maintain insurance because of increased protection. This continued availability of insurance in turn increases the likelihood that plaintiffs will actually receive damages, albeit limited damages, rather than pursuing collection from bankrupt, uninsured defendants.

The goal of tort law of deterring malpractice is unaffected by this statute, however. Although the threat of large monetary costs is removed from health care providers qualified under the Act, many penalties remain untouched. The accusation of malpractice before a panel or a court exacts costs in the form of social stigma, loss of prestige, embarrassment,

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[141] *Id.* at 112-113.

[142] *Id.* at 113.

[143] *See Cha*, 476 N.E.2d at 113.

[144] *See Medical Malpractice: The States Respond*, 9 Health Law Vigil 11, 18 (1986).

anxiety, and time. These costs cannot be easily legislated away. Indeed, the only alternative may be to cap the number of malpractice lawsuits at a specific level—a change not likely to occur without drastic change in the current attitude about justice.

The true deterrents to negligent behavior by a physician are probably the non-monetary costs of an accusation of medical malpractice, not the possibility of increased financial costs.[145] The accusation alone may be a sufficiently negative sanction to change a doctor's methods of practice. One result of the perceived medical malpractice crisis has been the practice of defensive medicine, the increased use of costly procedures and tests to foreclose accusations of malpractice.[146]

VI. Impact of Federal Law

Medical treatment decisions are not made in a vacuum. Increasingly, medical practice is affected by changes in the economics of practice. Prior to the advent of Medicare,[147] doctors and hospitals relied upon patients and private insurance for reimbursement. In 1965, Medicare came into being to pay for medical expenses for the elderly.[148] The goals of the program, to improve health care for the elderly by paying for specified services, have come into conflict with the restrictive attitude toward federal spending in the 1980's. Increases in the cost of medical care, whether from inflation or technological advances, and the perceived need for the federal government to contain those costs have led to significant changes in federal reimbursements under Medicare.

The Health Care Financing Administration (HCFA) reimburses hospitals for services covered by Medicare.[149] At the direction of Congress, HCFA has now developed prospective rating formulas designed to determine the amount of Medicare reimbursement according to the diagnosis-related group (DRG) category applicable to a patient.[150] Because reimbursement is no longer based on the cost of services rendered, hospitals are encouraged to keep their costs to a minimum.[151]

In addition to DRGs, quality control Peer Review Organizations (PRO's) have been established.[152] These organizations are made up of

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[145]Bell, *Legislative Intrusion into the Common Law of Medical Malpractice: Thoughts About the Deterrent Effect of the Tort Liability*, 35 Syracuse L. Rev. 939 (1984).

[146]*Id.*

[147]42 U.S.C. §§ 1395, 1395a to 1395xx (1982).

[148]*Id.*

[149]*Id.* § 1395ww.

[150]*See* 97 Stat. 65 (1983); 42 C.F.R. § 412 (1985).

[151]*See* Note, *Rethinking Medical Malpractice Law in Light of Medicare Cost-Cutting*, 98 Harv. L. Rev. 1004, 1006 (1985).

[152]*See* Gosfield, *Hospital Utilization Control by PROs: A Guide Through the Maze*, 2 Healthspan 3 (1985), for a general history of legislation concerning review of utilization of hospital services.

physicians and contract with the Department of Health and Human Services to review health care provided by hospitals and to validate reimbursements.[153] These reviews perform watchdog duties to insure that hospitals do not abuse the Medicare system.[154] The motivation for this legislation was also cost efficiency.[155] PRO review does provide some protection from liability; the law shields physicians and other health care providers from civil liability "on account of any action taken . . . in compliance with or reliance upon professionally developed norms of care and treatment applied by an organization under contract . . . ."[156] The degree to which this immunity will protect a doctor is uncertain, however.[157] The primary goal of the legislation is not to change malpractice liability, but to decrease costs.[158]

The philosophy underlying these measures directly conflicts with that of defensive medicine. Defensive medicine is an effort to protect against the accusation of malpractice by using every indicated procedure to diagnose and treat illness.[159] This practice is fundamentally opposed to the concept of minimizing service costs. In the world of reducing costs for services, defensive medical procedures may be the first to fall.[160] This change is already occurring in some public hospitals.[161]

The recent emphasis on cost-cutting in medical care may also affect the tort principle of standard of care. In Indiana, the standard of care is determined by a "modified locality rule."[162] The competence of medical care is evaluated in the context of the medical care rendered by physicians in the same or a similar locality.[163] The standard therefore is self-determined by the profession. In conjunction with advances in medical technology, heightened patient expectations, and the spread of defensive medicine, the standard of care has become increasingly higher.[164] This higher standard of care compounds the problem of increased costs. Physicians perform more tests to ward off malpractice suits, which, in

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[153]42 U.S.C. § 1320(c) (1982).

[154]Gosfield, *supra* note 152, at 6-7.

[155]*See* Kapp, *Legal and Ethical Implications of Health Care Reimbursement by Diagnosis Related Groups*, 1984 LAW, MED. AND HEALTH CARE 245, 245.

[156]42 U.S.C. § 1320(c)-6(c) (1982).

[157]Gosfield, *supra* note 152, at 8.

[158]*See Kapp*, *supra* note 155, at 245.

[159]Project, *The Medical Malpractice Threat: A Study of Defensive Medicine*, 1971 DUKE L.J. 939, 942-943.

[160]*See* Rosenblatt, *Rationing "Normal" Health Care: The Hidden Legal Issues*, 59 TEXAS L. REV. 1401 (1981).

[161]*Id.* at 1402.

[162]Kranda v. Houser-Norborg Medical Corp., 419 N.E.2d 1024, 1040 (Ind. Ct. App. 1981).

[163]Joy v. Chau, 177 Ind. App. 29, 36, 377 N.E.2d 670, 675 (1978).

[164]*See* Note, *supra* note 151, at 1009.

turn, increase the standard of care. This, in turn, increases the likelihood of allegations of malpractice if tests are not performed, thereby reinforcing the need to perform more tests. The new Medicare prospective reimbursement system breaks this circle.[165]

Now, the medical profession is confronted with a cost containment philosophy that has repercussions on the standard of care in the community. Although the community of doctors may consider tests or procedures appropriate, the cost-cutting pressures exerted by the federal government may influence a doctor's decisions regarding treatment. The federal changes are dictated by economic considerations. These considerations conflict with the historical medical ethic to spare no expense to treat a patient, which had been reinforced by tort law. While federal law demands that the benefit of additional tests be weighed against the costs, the prevailing attitude in tort cases minimizes this balancing. The effect of this economic balancing on tort law standards has yet to be determined.[166]

The conflicting philosophies of cost-containment and tort law arise from different perspectives. Cost-containment looks at the medical care system as a whole and institutes changes on a system-wide basis.[167] The decision-making process in a tort suit looks at a specific case and addresses problems on an individual basis.[168] As one commentator noted:

> [I]t is generally difficult to distinguish between medically indicated costcutting undertaken without regard for medical efficacy. The distinction becomes even more elusive when the criteria used to make it depend on whether one views the problem from the perspective of a legislature seeking to cut costs in general or that of a jury deciding whether malpractice was committed in a specific case.[169]

The conflict inherent in these different viewpoints will lead to conflicts in the responses generated by both the medical profession and the judicial system.[170]

Hospitals will become more susceptible to malpractice claims as cost-cutting measures influence care given to patients.[171] Where federal cost-cutting pressures are exerted on physicians, the hospital may be more likely to be allocated part of the liability. Of particular concern to society

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[165]*See supra* notes 147-158 and accompanying text.

[166]*See* Note, *supra* note 151, at 1009.

[167]*See* Rosenblatt, *supra* note 160, at 1422.

[168]*Id.*

[169]*See* Note, *supra* note 151, at 1013 (citations omitted).

[170]For discussion as to resolution of this conflict, see *id.* at 1017-19.

[171]For a good discussion of the impact of cost cutting measures on those eligible for Medicare and Medicaid, see Rosenblatt, *supra* note 160, at 1401.

will be the federal government's pressure on hospitals to monitor physicians and control decision-making regarding treatment. Whether this will subject hospitals to broader liability for patient care is yet to be determined.

It is also possible that patients who believe they have been harmed as a result of cost-cutting measures such as prospective payment will include insurers as defendants in malpractice suits. In a recent California case involving a prospective payment mechanism, a patient who was discharged from a hospital sooner than her physician initially recommended and who suffered a leg amputation due to complications that would have been detected had she stayed in the hospital named the third-party payer as a defendant in a negligence suit.[172] Although the appellate court found the insurer not liable in this case,[173] the holding does not preclude insurer liability in other circumstances.

VII. Conclusion

The Indiana legislature's reaction in 1975 to the rise in medical malpractice insurance costs resulted in a trade-off of time and amounts recovered for preserving the protection of insurance.[174] Although the Act contemplates a relatively short period for review of malpractice claims, implementation of the Act has caused significant delays.[175] However, neither the procedural roadblock the Act creates for plaintiffs nor the reality of delays has been sufficient to support a constitutional challenge to the Act.[176] Further, much of the delay can be controlled by assertion of the statutory provisions. However, the statutory solution offers not only opportunities to prepare for litigation, but also traps for those who are not familiar with the intricacies of the Act, including who is covered by the Act, what kind of actions are considered malpractice, and how the statute of limitations applies.

Although Indiana's legislative solution to the medical malpractice problem represents a change in attitudes about victim recoveries, it does not affect the deterrent goal of tort law. The deterrent goal is, however, affected by changes in federal law.[177] The federal government's encouragement of cost-containment in health care discourages practices that shield doctors and hospitals from accusations of medical malpractice.[178] Viewed in the context of the federal changes, Indiana mal-

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[172]Wickline v. State, 183 Cal. App. 3d 1175, 228 Cal. Rptr. 661 (1986).

[173]*Id.*

[174]*See supra* notes 4-14 and accompanying text.

[175]*See supra* notes 34-54 and 136-142 and accompanying text.

[176]*See supra* notes 136-142 and accompanying text.

[177]*See supra* notes 154-171 and accompanying text.

[178]*Id.*

practice reform takes on greater import. Although the Indiana Act's provisions for panel review and limitation of damages do not change the deterrents of negligent behavior,[179] the federal law does.

Yet, both state and federal law reflect similar changes in attitude, which taken together have a greater impact than if they stood alone. The state law represents a choice of affordable insurance and at least partial compensation for victims as opposed to full compensation recoverable from only a few deep pockets. The federal law represents a choice of economy at the risk of omissions in health care—care that might be provided if costs were not a barrier.

Although the parties involved would acknowledge the importance of providing the best quality health care, or full compensation where care is not the best, the changes represent an implicit acknowledgment of certain realities. Both federal and state legislatures have recognized the impact of the economics of medical care. Ultimately, it is this economic reality which any future steps toward reform must consider.

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[179]*See supra* notes 154-161 and accompanying text.

Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program

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I. INTRODUCTION

Since 1980, the federal government, states, and private purchasers of health care services have determined that the amount of resources devoted to purchasing health care services is too great. Consequently, the 1980's have witnessed unprecedented efforts by these purchasers to cut spending for health care services and to adopt payment strategies to purchase health care services more efficiently. For private purchasers, i.e., business, private insurance companies, and Blue Cross and Blue Shield plans, these strategies include chiefly preferred provider organizations[1] and prepaid health plans such as health maintenance organizations.[2] Similarly, states and the federal government have adopted comparable strategies for their public health insurance programs.[3] These strategies limit public expenditures for health care services chiefly through rate regulation.[4]

The underlying theory of nearly all of these public and private strategies is to put the providers of health care services, e.g., hospitals

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[1]A PPO is as an arrangement between selected providers and at least one group purchaser whereby the services of the providers are purchased for a specified group of individuals at a negotiated rate. *See* AM. HOSP. ASS'N, STATE REGULATION OF PREFERRED PROVIDER ORGANIZATIONS: A SURVEY OF STATE STATUTES (1984).

[2]In a prepaid health plan, the consumer or someone on his behalf pays a fixed amount to the provider, and in return, the provider furnishes any volume of covered health care services irrespective of their cost. A health maintenance organization is an example of a prepaid health plan. A prepaid health plan is distinguished from conventional health insurance in that the provider rather than the health insurance company is at risk for the cost of services to beneficiaries over and above the premiums.

[3]The Social Security Act authorizes state Medicaid programs to purchase health care services for certain groups of patients from specified providers on a prepaid basis. 42 U.S.C. § 1396 (1982 & Supp. 1985). To use this strategy, state Medicaid programs must ensure that the providers have a plan to manage the care of individual patients properly. *Id.* § 1396a(a).

[4]In rate regulation schemes, which are directed chiefly at institutional providers, the payer regulates the amount paid for a unit of services, i.e., the price per case as under the Medicare prospective payment system, or even the entire amount the program will pay an institution annually as under revenue caps or budget review strategies.

and physicians, at risk financially for the cost of services that exceed defined norms. This approach involves putting a limit on what the purchaser will pay for services in a given case or group of cases, with the result that if the provider's costs of the care exceed the limit, the provider must absorb the excess costs. The objective of these strategies is the same: to encourage providers to become more conscious of the costs of treating patients and to use less resources and thus incur fewer costs in the treatment of patients.

However, these strategies fundamentally change the nature of the decision-making of health care providers with respect to the medical treatment of individual patients. Simply, providers must consider the cost of the treatment as well as its efficacy. Specifically, providers can no longer adhere to what Dr. Avedis Donabedian has called an absolutist standard of health care quality in which providers specify care based on what they consider best for patients, even if benefits are quite incremental, without regard to costs.[5] Also, the specter of financial liability for excessive services on the part of the provider directly is a troublesome ingredient of the decision making process as it pits the provider's self-interest squarely against the patient's need for an above average amount of health care services in a given instance. This raises the possibility that the quality of medical treatment may be compromised. This possibility, which must be addressed in the design and implementation of any purchasing strategy that places the provider at risk financially, presents a host of important ethical and, in the case of public programs, political issues, some of which will be explored in this Article and this symposium.[6]

This Article delineates the central issues presented when government adopts a strategy to purchase health care services more efficiently and to reduce the resources it devotes to health care. It reviews how the American health care system reached the point where purchasers of health care services have almost uniformly decided to curtail the resources they commit to purchasing health care services and the resulting perception among providers, patients, and the public that hard choices about the allocation of limited resources are now required.

But, the chief objective of this Article is to analyze how the Medicare

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[5]Donabedian, *Quality, Cost, and Clinical Decisions*, 468 ANNALS 196, 200 (1983).

[6]This dilemma and its philosophical implications have been analyzed by several scholars. *See* Cassel, *Doctors and Allocation Decisions: A New Role in the New Medicare,* 10 J. HEALTH POL. POL'Y & L. 549 (1985); Kapp, *Legal and Ethical Implications of Health Care Reimbursement by Diagnosis Related Groups*, 12 L. MED. & HEALTHCARE 245 (1984); Mariner, *Diagnosis Related Groups: Evading Social Responsibility*?, 12 L. MED. & HEALTHCARE 243 (1984); Morriem, *The MD and the DRG*, HASTINGS CENTER REP., June 1985, at 19; Veatch, *DRG's and the Ethical Reallocation of Resources*, HASTINGS CENTER REP., June 1986, at 32.

prospective payment system makes fair decisions about the allocation of hospital services to Medicare beneficiaries. In this reform of the payment methodology for hospital services,[7] Congress endeavored to purchase health care services more efficiently for the nation's elderly and disabled and consequently put hospitals at risk financially for costs of treatment that exceed defined norms. In designing the administrative structure for the prospective payment system, Congress specifically addressed the three critical problems facing public health insurance programs that endeavor to curtail expenditures by putting providers at risk financially: (1) how to make fair decisions at the societal level as to what resources in the control of government should be devoted to the health care of the program's beneficiaries, (2) how to ensure that providers, who are at risk for especially costly services, make fair decisions about what resources should be used to care for beneficiaries, and (3) how to protect adequately beneficiaries' interests in obtaining health care services under the Medicare program.

II. The Central Issues

How much of society's resources should be devoted to health care and how those resources should be distributed among members of society — particularly the more disadvantaged—are fundamental questions of distributive justice beyond the scope of this Article.[8] But these questions are not just abstract philosophical questions of remote importance. They are concrete questions that continually and directly face American health policy. In particular, these questions confront federal and also state policy makers daily as they address the health care needs of their citizens and as they design and implement public health insurance programs. Thus it is useful to explore some of the central issues involved with the general question of how much of society's resources should be devoted to health care and how those resources should be distributed among society's members before reviewing the history of how this nation has endeavored to resolve these issues generally and in the context of the Medicare program.

First and foremost is the issue of whether health care is such an important societal good that it should be accorded special treatment vis-a-vis other societal goods competing for society's resources. Second, who

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[7]Social Security Amendments of 1983, Pub. L. No. 98-21, tit. VI, § 601(c)(1), 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww (Supp. 1985)).

[8]*See, e.g.*, N. Daniels, Just Health Care, 1-74 (1985); Daniels, *Rights to Health Care and Distributive Justice: Programmatic Worries*, 4 J. Med. & Phil. 174 (1979); Fried, *Rights and Health Care - Beyond Equity and Efficiency*, 293 New Eng. J. Med. 241 (1975); Miller & Miller, *Why Saying No to Patients in the United States Is So Hard: Cost Containment, Justice and Provider Economy*, 314 New Eng. J. Med. 1380 (1986).

is making the decisions about the amount and allocation of these health care resources at the societal level and also at the individual level? Third, what consumer interests in health and health care services should be protected while making those choices?

Decisions about the amount and allocation of medical resources are made in two contexts, the societal context and the individual context. The societal context involves decisions about the amount of society's resources that should be allocated to health care services vis-a-vis other unrelated needs, as well as decisions as to what groups these medical resources should be targeted in order to assure preservation or enhancement of the lives of society's members in the aggregate, i.e., "statistical lives."[9] The individual context is fundamentally different; it involves whether and how society's resources should be dedicated to meet the specific health care needs of identifiable individuals.

With respect to whether health is of such value that it should be treated specially, the philosopher Norman Daniels has characterized the key aspects of this issue in developing a philosophical theory of health care:

> In short, a theory of health care needs must come to grips with two widely held judgments: that there is something especially important about health care and that some kinds of health care are more important than others.[10]

Whether it is even philosophically appropriate to give health care special status is a troubling question of distributive justice. But it is fair to say that this society has made a collective judgment that health care has special value and that some measures, e.g., public health insurance programs, over and above market forces should be invoked to ensure that this good is widely distributed. The federal and state governments have concurred in this assumption, albeit with waning enthusiasm in

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[9]*See* Blumstein, *Constitutional Perspectives on Governmental Decisions Affecting Human Life and Health*, 40 L. & CONTEMP. PROBS. 231 (1976) [hereinafter Blumstein, *Constitutional Perspectives*]; Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSRO's*, 70 NW. U.L. REV. 6, 22-23 (1975) [hereinafter Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs*]; *see also* Fried, *The Value of Life*, 82 HARV. L. REV. 1415 (1969).

A "statistical life" is basically a measure representing one unit of human existence, whereas an identifiable life is recognized as a life of a specific human being. Havighurst and Blumstein more aptly articulated the difference between "statistical" and "identifiable" lives in colorful and precise examples of these concepts: an identifiable life is an "intercontinental balloonist lost at sea" whereas statistical lives are those which "predictably will be lost as a result of a societal undertaking such as maintenance of an automobile-based economy or construction of a bridge or tunnel." Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs, supra* at 21-22.

[10]Daniels, *Health-Care Needs and Distributive Justice*, 10 PHIL. & PUB. AFF. 146 (1981); *see also* N. DANIELS, *supra* note 8, at 1-17.

recent years. However, important evidence suggests that the American public does not believe that this nation and its government should limit their financial and ideological commitment to ensuring high quality, accessible health care services for those in need.[11] Nevertheless, the degree to which this nation and its governments should treat health care as special and invoke special measures to assure wide distribution of health care services as well as the nature of these special measures have been the central themes of health policy since 1965.

Daniels' second observation raises the more important inquiry from a practical perspective and perhaps the key ethical dilemma for the American health care system today. Clearly, all health care services are not the same and have varying degrees of worth, especially when compared with other societal needs. This dilemma is perhaps best exemplified by some of the trade-offs that the federal government has made with respect to resources devoted to health care needs of infants. For example, since 1981, the federal government has reduced funding for prenatal health and nutrition programs for millions of mothers and children[12] while at the same time has subsidized costly organ transplants of questionable long term benefit for selected babies through waivers of Medicaid program requirements on a seemingly ad hoc basis.[13] This dilemma raises the second issue involved with making hard choices—who should make these decisions both in the societal and individual contexts.

The decision-makers are a disparate group. In the societal context, the federal and state governments are the primary decision-makers. In the individual context, the decision-makers fall into two categories: those who provide services and those who pay for services. The providers include, chiefly, physicians and hospitals. The payers are insurance companies, Blue Cross and Blue Shield plans, business, and other entities that pay for the health services provided to specified groups of individuals. Payers include individual patients, also an important group given that twenty-eight percent of the nation's personal health care expenditures are made by individuals.[14] Payers also include the federal and state governments in their capacity as administrators of the Medicare, Medicaid, and other public health insurance programs.

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[11]Blendon & Altman, *Public Attitudes About Health-Care Costs: A Lesson in National Schizophrenia*, 311 NEW ENG. J. MED. 613 (1984); *see also* Ferguson & Rogers, *The Myth of America's Turn to the Right*, ATL. MONTHLY, May 1986, at 43.

[12]Mundingher, *Health Services Funding Cuts and the Declining Health of the Poor*, 313 NEW ENG. J. MED. 44 (1985).

[13]*See, e.g.*, Wessell, *Medical Quandary Transplants Increase, and So Do Disputes over Who Pays Bills*, Wall St. J., Apr. 12, 1984, at 1; Friedman & Richards, *Life and Death in a Policy Vacuum*, HOSPITALS, May 16, 1984, at 79; Rust, *Transplant Success Stirs Debate on Coverage*, AM. MED. NEWS, Oct. 21, 1983, at 1.

[14]Levit, Lazenby, Waldo & Davidoff, *1984 National Health Expenditures*, 7 HEALTH CARE FINANCING REV. 1 (1985) [hereinafter *National Health Expenditures, 1984*].

The respective roles of these decision-makers have been the focus of considerable attention in the health policy debate in recent years. The question is whether decisions about the content and allocation of health care resources are best made explicitly on an aggregate level by government as the representative of its citizens, or implicitly and unsystematically on an individual level either through the market and within the context of the provider-patient relationship whenever possible.[15] The liberal position assigns the federal government the predominant role in making decisions on a societal level about what national resources should go to health care services versus competing needs and also, through selection of federally-dominated national health insurance benefits, what health care services should be available to patients at the individual level. The conservative view maintains that health care services should be delivered on a private basis whenever possible and that allocation decisions on the societal level as well as the individual level should be made collectively through the operation of the market with government intervening only as a last resort to correct manifest injustice.

The final issue is what are the interests and, indeed, rights of the individuals who need health care services and are affected by these decisions. Moreover, what kind of protection does a decision-making process afford an individual patient who may be adversely affected by a decision, whether he be one gravely ill individual who is denied expensive, life-prolonging treatment or a member of a group who benefits from a government health service program?

Much ink has been spilled over whether individuals have a right to health care in a moral or legal sense, and if so, what this right means in terms of the responsibility of government, other payers, and providers to furnish health care services.[16] The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavior Research declined to declare that health care is either a legal or moral right, but rather chose to frame its analysis of securing access to health

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[15]The question of who should make these choices, the market or government, has been debated and analyzed extensively in a published dialogue between Professors James Blumstein and Rand Rosenblatt. *See* Blumstein, *Distinguishing Government's Responsibility in Rationing Public and Private Medical Resources*, 60 TEX. L. REV. 899 (1982); Blumstein, *Rationing Medical Resources: A Constitutional, Legal and Policy Analysis*, 59 TEX. L. REV. 1345 (1981) [hereinafter Blumstein, *Rationing Medical Resources*]; Rosenblatt, *Rationing "Normal" Health Care: The Hidden Legal Issues*, 59 TEX. L. REV. 1401 (1981); Rosenblatt, *Rationing "Normal" Health Care Through Market Mechanisms: A Response to Professor Blumstein*, 60 TEX. L. REV. 919 (1982); *see also* Mehlman, *Rationing Expensive Lifesaving Treatments*, 1985 WIS. L. REV. 239.

[16]*See, e.g.*, K. DAVIS & C. SCHOEN, HEALTH AND THE WAR ON POVERTY: A TEN YEAR APPRAISAL 2-7 (1978); Buchanan, *The Right to a Decent Minimum of Health Care*, 13 PHIL. & PUB. AFF. 55 (1984); Siegler, *A Right to Health Care: Ambiguity, Professional Responsibility, and Patient Liberty*, 4 J. MED. & PHIL. 148 (1979).

"in terms of the special nature of health care and of society's moral obligation to achieve equity, without taking a position on whether the term 'obligation' should be read as entailing a moral right."[17] Indeed, it is hardly useful to talk about the interests of consumers in health care as a right because, as a practical matter, interests are protected and enforceable as rights only when there is an associated remedy accorded by law.

From a legal perspective, it is clear that one does not have an enforceable, legal "right" to health care. The Supreme Court has ruled that the federal Constitution does not recognize any such "right" to medical care.[18] The federal Constitution does protect the entitlement interest of beneficiaries in the federal and state Medicare and Medicaid programs, but only to the extent outlined in the enabling legislation for these programs.[19] However, as with any entitlement program, the nature of the entitlement interest can be limited by subsequent legislative amendment and the nature of the constitutional protection accorded is that of procedural due process.[20]

Certainly, citizens do not have so powerful an interest or right that they can obtain high quality services of any type on demand. However, it is widely held, as a corollary of the tenet that health care is special, that individuals have some interest in obtaining health care services although that interest is subject to legal protection only in the context of an entitlement created by, and then only to the extent authorized by, the government in its design and lawful implementation of the entitlement program. Thus, decision-makers have considerable power in making

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[17]I PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECURING ACCESS TO HEALTH CARE: THE ETHICAL IMPLICATIONS OF DIFFERENCES IN THE AVAILABILITY OF HEALTH SERVICES 32 (1983) [hereinafter PRESIDENT'S COMMISSION, SECURING ACCESS TO HEALTH CARE].

[18]*See* Harris v. McRae, 448 U.S. 297 (1980); Mahrer v. Roe, 432 U.S. 464 (1977) (involving state obligations to provide certain benefits under their Medicaid programs). The possible exception is a right of prisoners to necessary medical care on grounds that denial of such care is cruel and unusual punishment proscribed by the eighth amendment. Estelle v. Gamble, 429 U.S. 97 (1976). *See* PRESIDENT'S COMMISSION, SECURING ACCESS TO HEALTH CARE, *supra* note 17, at 33; Blumstein, *Constitutional Perspectives, supra* note 9, at 257-70; Blumstein, *Rationing Medical Resources, supra* note 15, at 1377-81.

It is worth noting that at least one state supreme court has interpreted its state constitution as according a right to certain health care services which the state had to provide. Callahan v. Carey, N.Y.L.J., Dec 11, 1979, at 10, col. 5 (Sup. Ct. N.Y. County 1979); *see also* Malone, *Homelessness in a Modern Urban Setting*, 10 FORDHAM URB. L. J. 749 (1982).

[19]*See, e.g.*, O'Bannan v. Town Court Nursing Center, 447 U.S. 773 (1980); Gray Panthers v. Schweiker, 652 F.2d 146 (D.C. Cir. 1980).

[20]*See* Blumstein, *Rationing Medical Resources, supra* note 15, at 1369-72; *see also* Note, *Due Process in the Allocation of Scarce Lifesaving Medical Resources*, 84 YALE L.J. 1734 (1975).

decisions about the composition and allocation of health care services to individuals.

Finally, it should be noted that there is constant tension between making allocation decisions at the societal level and at the individual level that inevitably confuses decision-makers and that results in considerable irrationality in the distribution of medical resources. This tension exists between the need and effort to allocate scarce medical resources in the societal context and the observance of the strongly-held societal value of assuring preservation of "identifiable" lives in the individual context. This tension has been aptly described:

> Decisions which seem economically necessary and ethically appropriate at the first [macro-prospective] level force choices at the second [micro-immediate] which seem ethically unacceptable (and vice-versa—aggregating up from the micro-immediate level in response to ethical imperatives seems to result in a requirement at the macro-prospective level which is economically unacceptable).[21]

This tension is aggravated when reductions in resources mandate allocation policies that deny services to a specific individual with a life-threatening need. American society values individual life so deeply that it may not be able to tolerate politically or morally the denial of medical care to identifiable individuals in need when government policies and economic realities would curtail such costly health care services at the societal level. Government as representative of its citizens and administrator of public health insurance programs is often confronted with this tension and the hard choices it generates. Congress endeavored to address this tension and the resulting hard choices in its design of the administrative structure for the Medicare prospective payment system for hospitals.

III. Reaching the Point of Hard Choices

A. Some History

In 1965, the Congress of the United States established the Medicare and Medicaid programs to address the problem of restricted access to health care services for the elderly and poor because of the prohibitive cost of many health care services for these disadvantaged groups.[22] This

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[21]Zechauser, *Coverage for Catastrophic Illness*, 21 Pub. Pol'y 149, 163 n.24 (1973) (quoting Carl Stevens); *see* Blumstein, *Constitutional Perspectives*, *supra* note 9, at 254 n.134.

[22]Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I §§ 101-111, 121-122, 79 Stat. 291-360 (codified as amended at 42 U.S.C. §§ 1395, 1396 (1982 & Supp. 1985)); *see also* S. Rep. No. 404, 89th Cong., 1st Sess:, *reprinted in* 1965 U.S. Code Cong. & Admin. News 1943.

congressional action confirmed that modern medicine—with its sophisticated scientific and technological base—had come of age.[23] Never had medicine enjoyed greater prestige. Virtually overnight, penicillin and the Salk vaccine had wiped out diseases that had plagued mankind since recorded history. The discovery of DNA and other startling advances in biomedical research in the early 1950's ushered in a new era promising even greater medical breakthroughs and fostering the public perception that the cure for all illness was within reach.

Surely this phenomenon of modern medicine was truly a "good thing" that should be made available to all Americans. After World War II and in a fashion unprecedented for treatment of a predominantly private activity, Congress committed federal resources to a whole range of health related endeavors. In 1946, Congress established the Hill-Burton program to finance the construction of hospitals and health care facilities, with the requirement that assisted facilities provide a reasonable volume of health care services to the poor and be open to all people in the institution's service area.[24] Congress also established the National Institutes of Health to coordinate the enormous federal expenditure for basic biomedical research.[25] The 1950's and 1960's also saw substantial federal support of academic medical centers for medical and allied health education and biomedical research training.[26] But, the culmination of this federal commitment to ensuring high quality and accessible health care services was establishment of the Medicare and Medicaid programs in 1965.

Medicare, a federal social insurance program administered by the Department of Health and Human Services, provides hospital insurance for hospital and extended care services as well as supplementary medical insurance for physician and associated services to the aged, disabled, and certain individuals with end stage renal disease.[27] Medicaid, a welfare program administered by the states pursuant to federal guidelines, pro-

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[23]*See* P. STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE, 335-78 (1982).

[24]Hospital Survey and Construction Act, Pub. L. No. 79-725, 60 Stat. 1040 (1946) (codified as amended at 42 U.S.C. §§ 291-291o (1982 & Supp. 1985)). *See generally* Blumstein, *Court Action Agency Reaction: The Hill-Burton Act as a Case Study*, 69 IOWA L. REV. 1227 (1982); Rose, *Federal Regulation of Services to the Poor Under the Hill-Burton Act: Realities and Pitfalls*, 70 NW. U.L. REV. 168 (1975); Rosenblatt, *Health Care Reform and Administrative Law: A Structural Approach*, 88 YALE L.J. 243 (1978).

[25]Pub. L. No. 95-622, tit. II, § 241(a)(1), 92 Stat. 3424 (1978) (codified as amended at 42 U.S.C. § 281 *et seq.* (1982 & Supp. 1985)); *see also* Fredrickson, *Health and the Search for Knowledge*, in DOING BETTER AND FEELING WORSE: HEALTH IN THE UNITED STATES 159 (J. Knowles ed. 1977).

[26]*See generally* Ebert, *Medical Education in the United States*, in DOING BETTER AND FEELING WORSE: HEALTH IN THE UNITED STATES 171 (J. Knowles ed. 1977).

[27]In 1972, Congress added the disabled and individuals with end stage renal disease to those eligible for Medicare. Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 299I, 86 Stat. 1329 (codified as amended at 42 U.S.C. § 1395 (1982 & Supp. 1985)).

vides hospital, physician, and nursing home services to persons eligible for categorical assistance programs under the Social Security Act[28] and who, but for income, otherwise meet the eligibility criteria for these categorical assistance programs.[29] The Medicare program is financed through trust funds comprised chiefly of proceeds from a payroll tax and insurance premiums and, to a minimal extent in the case of the supplementary medical insurance, Congressional appropriations from general revenues; Medicaid is financed out of federal appropriations that match state appropriations for this program.[30] These government health insurance programs now serve over 50 million people.[31] These two programs have had a tremendous impact on the improvement of health status among the elderly and poor, demonstrated by sharp decreases, over thirty percent, in mortality rates for diseases that afflicted the aged and poor disproportionately, e.g., diabetes, heart disease, stroke, and pneumonia, as well as substantial reductions in infant mortality rates.[32] However, at no time did these two programs cover all persons in need and, currently, at least fifteen percent of all Americans have no health insurance coverage.[33]

Medicare and Medicaid represented an enormous expression of confidence in a modern, scientifically-based, health care system. In designing these programs, Congress was guided almost exclusively by concerns and interests of the architects of this new health care system — physicians and hospitals.[34] The hospital industry and the medical profession dictated

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[28]There are two categorical assistance programs under the Social Security Act: Aid to Families with Dependent Children, for poor mothers and children, 42 U.S.C. §§ 601-615 (1982 & Supp. 1985), and Supplemental Security Income Program for the indigent aged, disabled, and blind, *id.* §§ 1381-1394.

[29]*Id.* § 1396a(a)(10)(c); *see also* K. Davis & C. Schoen, *supra* note 16, at 52-56. States must provide Medicaid benefits to those on categorical assistance programs; however, they have the option of adopting a medically needy program. 42 U.S.C. §§ 1396a(a)(10)(c), 1396d(a) (1982 & Supp. 1985). Over half of the states have a medically needy program despite marked cut-backs in federal matching funds for state Medicaid programs.

[30]*See* 42 U.S.C. §§ 1395i, 1395t (1982 & Supp. 1985) (Medicare trust fund provisions); *id.* § 1396b (Medicaid state appropriations provisions).

[31]*National Health Expenditures, 1984*, *supra* note 14.

[32]*What Medicaid and Medicare Did—and Did Not—Achieve,* Hospitals, Aug. 1, 1985, at 41-42 (interview with Karen Davis); *see also* Davis & Reynolds, *The Impact of Medicare and Medicaid on Access to Medical Care*, in The Role of National Health Insurance in the Health Service Sector 391 (R. Rosett ed. 1976).

[33]Mundingher, *supra* note 12, at 44; *see* Davis & Rowland, *Uninsured and Underserved: Inequities in Health Care in the U.S.*, in 3 President's Commission, Securing Access to Health Care, *supra* note 17, at 55.

[34]*See generally* J. Feder, Medicare: The Politics of Federal Hospital Insurance (1977); T. Marmor, The Politics of Medicare (1973); Cohen, *Reflections on the Enactment of Medicare and Medicaid*, 7 Health Care Fin. Rev. 3 (Supp. 1985).

the benefit packages and payment methodologies for these program and even retained control over who among their ranks would participate in these programs.[35] Further, the Medicare and Medicaid statutes assured that the structure of and key relationships within the health care system would be unaffected by these programs, with such measures as the guarantee of beneficiaries' freedom of choice to select their physicians and other health care providers.[36] Indeed, not interfering with the practice of medicine in any health care institutions was stated as a central policy in the Medicare program in the first section of the Medicare statute:

> Nothing in this title 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 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 or any such institution, agency or person.[37]

Perhaps most important, the Medicare and Medicaid programs gave physicians and hospitals almost complete autonomy in setting the level of payment for services provided to their beneficiaries, chiefly because of considerable political opposition to the programs from providers. According to Wilber Cohen, the Secretary of the Department of Health, Education and Welfare when the Medicare and Medicaid programs were adopted, at the time, "[t]he ideological and political issues were so dominating that they precluded consideration of issues such as reimbursement alternatives and efficiency options."[38]

Initially, both Medicare and Medicaid paid hospitals the costs, as calculated by hospitals, of providing services to beneficiaries with the only prescription that the costs be "reasonable."[39] Medicare paid phy-

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[35]For example, accreditation by the Joint Commission on Accreditation of Hospitals, the private accrediting body appointed by the hospital industry and the medical profession, would be sufficient to demonstrate a hospital's eligibility to participate in the Medicare program. 42 U.S.C. § 1395bb (1982 & Supp. 1985). *See generally* Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. REV. 835 (1983).

[36]*See* 42 U.S.C. §§ 1395a, 1396a(a)(23) (1982 & Supp. 1985).

[37]*Id.* § 1395a.

[38]Cohen, *supra* note 34, at 5.

[39]Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1395(f)(b), 1395x(v) (1982 & Supp. 1985)) (Medicare); *id.* at § 121(a) (codified as amended at 42 U.S.C. § 1396(a)(10) (1982 & Supp. 1985)) (Medicaid). Congress suggested that reimbursement methodologies of private insurance companies should guide the Medicare program in development of Medicare's reimbursement methodology:

sicians eighty percent of the reasonable, customary, or prevailing charge for covered services and allowed physicians to bill patients directly for their full charge under the traditional fee-for-services arrangement with patients then receiving payment from Medicare.[40] In contrast, Medicaid has always been stricter in its reimbursement for physicians, requiring them to accept assignment of Medicaid benefits from their patients and allowing states to set payment rates quite low.[41]

The Medicare and Medicaid programs changed the complexion of the American health care system fundamentally by transforming the cost and quality of accessible health care from basically a private matter to a matter of public concern. With Medicare and Medicaid, the federal government and also the states assumed a major responsibility for assuring access to health care services for disadvantaged groups, a significant departure from past policy of viewing the provision of medical care to these groups as primarily a local and voluntary effort. In addition, with these programs, the federal government and also the states assumed responsibility for the problem of what to do about the increasing cost of health care services.

> The bill provides that the payment to hospitals and other providers of services shall be equal to the reasonable cost of services and that the methods to be used and the items to be included in determining the cost shall be developed in regulations of the Secretary in accordance with the provisions of the bill.

S. REP. No. 404, 89th Code Cong., 1st Sess., *reprinted in* 1965 U.S. CONG. & ADMIN. NEWS 1943, 1976.

Initially, state Medicaid programs had to observe Medicare cost reimbursement principles for paying hospitals. Social Security Amendments of 1965, Pub. L. No. 89-97, § 121(a), 79 Stat. 286. Over time, Congress gave states greater flexibility in structuring Medicaid hospital payment methods and allowed paying hospitals less than Medicare. Social Security Amendments of 1972, Pub. L. No. 92-603, § 232(a), 86 Stat. 1329; Omnibus Reconciliation Act of 1981, Pub. L. No. 97-35, §§ 2171-2178, 195 Stat. 357. Also, in the Omnibus Reconciliation Act of 1981, Congress authorized states to curtail beneficiaries' choice of hospital providers under certain circumstances. *Id.* § 2175.

[40]Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286 (codified as amended at 42 U.S.C. § 1395*l*(a) (1982 & Supp. 1985)). In recent years, physician reimbursement has come under increasing regulation, and now there are greater incentives for physicians to accept assignment of Medicare benefits from their patients as payment in full as well as freezes and other limits on the amount of payment for physicians' services. *See* Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2306, 98 Stat. 494 (codified as amended at 42 U.S.C. § 1395u(b) (Supp. 1985)). *See* American Medical Ass'n v. Heckler, 606 F. Supp. 1422 (S.D. Ind. 1985), in which the American Medical Association and Indiana doctors unsuccessfully challenged this freeze on constitutional and other grounds.

[41]42 U.S.C. § 1396a(45), 1396k (1982 & Supp. 1985). As a result of these restrictive policies and practices, few physicians take Medicaid patients. These patients then must rely chiefly on hospital outpatient clinics and other facilities that cater specifically to the indigent for physicians' services. *See* Mitchell & Cromwell, *Access to Private Physicians for Public Patients: Participation in Medicaid and Medicare*, in 3 PRESIDENT'S COMMISSION, SECURING ACCESS TO HEALTH CARE, *supra* note 17, at 105.

The Medicare and Medicaid programs generated enormous demand for health care services and with this increased demand came sharp and continuing increases in the cost of health care services.[42] The seriousness of the cost problem surfaced shortly after the inauguration of the Medicare and Medicaid programs[43] and has dominated the health policy debate ever since. Of greatest concern were a rate of inflation in health care costs far exceeding that of the general economy, uncontrolled rise in federal and state budgetary expenditures in public health insurance programs to the exclusion of other public commitments, and the fact that health care commanded an ever greater proportion of the nation's resources as well.[44]

The federal government and the states became concerned about escalating costs of the Medicare and Medicaid programs and explored numerous cost containment strategies. Congress authorized waivers of Medicare and Medicaid program requirements to test cost-saving methodologies for paying for hospital services under these programs, and the Department of Health, Education and Welfare inaugurated experiments in several states to test the cost-effectiveness of prospective payment methodologies.[45] Several states adopted programs to regulate rates of hospitals and other health care institutions, and many of these state programs include Blue Cross, other private payers, and even Medicare.[46] Also, in the late 1960's and early 1970's, about one-third of the states

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[42]Gornick, Greenberg, Eggers & Dobson, *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, 7 HEALTH CARE FIN. REV. 13, 35-45 (Supp. 1985).

[43]*Proposed Medicare Reimbursement Formula: Hearings Before the Senate Comm. on Finance*, 89th Cong., 2d Sess. (1966); STAFF OF SENATE COMM. ON FINANCE, MEDICARE AND MEDICAID: PROBLEMS, ISSUES, AND ALTERNATIVES, 91st Cong., 1st Sess. 53, 140-43 (Comm. Print 1970).

[44]Between 1967 and 1983, the rate of increase in hospital costs was 17.2% and did not abate until 1984, the first year of the prospective payment system. Gornick, *supra* note 42, at 35-45. The Medicare program consumed an increasingly large portion of the federal budget during these periods. Further, the health care system commanded a larger portion of the nation's resources. In 1965, the percentage of the gross national product devoted to health care was about 6% and in 1984 that percentage was 10.8%. *National Health Expenditures, 1984*, *supra* note 14, at 1.

[45]Social Security Amendments of 1967, Pub. L. No. 90-248, § 402, 81 Stat. 821; Social Security Amendments of 1972, Pub. L. No. 92-603, § 222(a), 86 Stat. 1329; *see also* DEP'T OF HEALTH & HUMAN SERVICES, HEALTH CARE FINANCING ADMIN., HEALTH CARE FINANCING GRANTS AND CONTRACTS REPORT, THE NATIONAL HOSPITAL RATE-SETTING STUDY: A COMPARATIVE REVIEW OF NINE PROSPECTIVE RATE-SETTING PROGRAMS (1980).

[46]*See* Esposito, Hupfer, Mason & Rogler, *Abstracts of State Legislated Hospital Cost-Containment Programs*, 4 HEALTH CARE FIN. REV. 129 (1982).

As of 1986, ten states have adopted mandatory rate regulation programs involving payers besides Medicaid: New York, New Jersey, Maryland, Massachusetts, Washington, Wisconsin, Connecticut, Maine, and West Virginia. Some states have Medicare waivers to operate all payer systems. States can obtain waivers to set up their own all payer rate

adopted capital expenditure review programs to regulate costly capital investment in health care facilities and services on the theory that excess capital investment was a major cause of the escalation of all health care costs.[47]

In the Social Security Amendments of 1972, Congress adopted several regulatory strategies to address the problem of cost inflation in the Medicare and Medicaid programs. Borrowing from state approaches to rate regulation, Congress authorized HEW to impose a limit on the routine costs that Medicare paid hospitals.[48] These amendments also supported state capital expenditure review programs by authorizing the Medicare program to withhold reimbursement for capital costs for any projects disapproved under a state certificate-of-need program.[49] In addition, these amendments established a professional peer review program to review the utilization of hospital services provided beneficiaries of the Medicare and Medicaid programs.[50] Regarding Medicaid, Congress accorded states greater flexibility to structure and reduce payments to health care institutions for the care of Medicaid beneficiaries.[51]

In 1974, Congress enacted the National Health Planning Resources and Development Act of 1974.[52] This statute required all states to establish health planning and certificate-of-need programs to control capital expenditure by health care facilities and assure rational distribution of health care services. Federally-mandated health planning and certificate-of-need programs represented a comprehensive federal effort to compel states to regulate the distribution of health care services on a local and state-wide level.[53]

Nevertheless, throughout the 1960's and 1970's, the federal government and also the states to varying degrees remained committed to the ideal of a strong government role in ensuring access to health care services for the aged, disabled, and poor through public health insurance programs. Indeed, the federal government under both Republican and

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setting programs and opt out of the Medicare prospective payment system. *See* AM. HOSP. ASS'N, LEGAL DEVELOPMENTS REPORT NO. 1: HOW STATES CAN OPT OUT OF THE FEDERAL MEDICARE DRG SYSTEM: A SUMMARY OF LEGAL ISSUES (1983).

[47]B. LEFKOWITZ, HEALTH PLANNING: LESSONS FOR THE FUTURE 13 (1983).

[48]Social Security Amendments of 1972, Pub. L. No. 92-603, § 223, 86 Stat. 1329 (codified as amended at 42 U.S.C. §1395x(v)(1)(A) (1982 & Supp. 1985)).

[49]*Id.* § 221(a) (codified as amended at 42 U.S.C. § 1320a-1 (1982 & Supp. 1985)).

[50]*Id.* § 249F(b). This program has been terminated and another peer review program established in its place. *See infra* notes 135-42 and accompanying text.

[51]Social Security Amendments of 1972, Pub. L. No. 92-603, § 232(a), 86 Stat. 1329 (codified at 42 U.S.C. § 1396(a) (1982 & Supp. 1985)).

[52]National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (codified as amended at 42 U.S.C. § 300K (1982 & Supp. 1985)).

[53]This program also established guidelines for the appropriate levels of certain health care services. *See id.* § 3 (codified as amended at 42 U.S.C. § 300k-t (1982)).

Democratic administrations was prepared to expand this commitment and provide health insurance coverage to all Americans through a national health insurance plan.[54] The only barrier to this goal was the serious problem of hospital cost containment and the concomitant fear that national health insurance would be prohibitively expensive.[55]

But also during this period, a consensus developed among federal and state policy makers, scholars, and other observers that the health care system was wasteful in its use of resources and experienced an inordinately high rate of inflation without a corresponding improvement in the health status of the population.[56] This phenomenon was particularly troubling given the other types of government services that could have been provided with the same funds.[57] Three factors were seen as causes for this waste and inflation. First were payment methodologies that paid providers basically the costs they incurred on their charges for providing services.[58] This contained incentives for overutilization of services and the resulting conception and expectation of high quality medical care as being any care that might benefit, regardless of cost.[59] The second factor was increases in costly medical technology.[60] The third factor was the

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[54]*See* HOUSE SUBCOMM. ON HEALTH OF THE COMM. ON WAYS AND MEANS, NATIONAL HEALTH INSURANCE RESOURCE BOOK, 94th Cong., 2d Sess. (1976); K. DAVIS, NATIONAL HEALTH INSURANCE: BENEFITS, COSTS, AND CONSEQUENCES (1975); NATIONAL HEALTH INSURANCE: WHAT NOW, WHAT LATER, WHAT NEVER (M. Pauly ed. 1980).

[55]The Carter Administration, to prepare the way for enactment of its National Health Plan, introduced two unsuccessful hospital cost containment bills in Congress. These bills proposed establishing a national rate regulation program for all payers on the theory that this regulation would keep hospital costs under control when the national health insurance program with its increased demand for services was implemented. *See* Wing & Silton, *Constitutional Authority for Extending Federal Control over the Delivery of Health Care,* 57 N.C.L. REV. 1423 (1979).

[56]*See* DOING BETTER AND FEELING WORSE: HEALTH IN THE UNITED STATES (J. Knowles ed. 1977); HOSPITAL COST CONTAINMENT: SELECTED NOTES FOR FUTURE POLICY (M. Zubkoff, L. Raskin & R. Hanft eds. 1978).

[57]For example, in 1976, Medicare program analysts estimated that with the $4 billion for new technology for Medicare patients in 1976, the federal government could have brought all aged persons above the poverty line or provided rent to raise two million elderly from substandard to standard housing, brought all the elderly above the lowest accepted food budget, or provided eyeglasses and hearing aids to all in need. *See* Warner, *Effects of Hospital Cost Containment on the Development and Use of Medical Technology*, 56 MILBANK MEMORIAL FUND Q./HEALTH AND SOCIETY 187, 188 (1978).

[58]*See* Biles, Schramm & Atkinson, *Hospital Cost Inflation Under State Rate-Setting Programs*, 303 NEW ENG. J. MED. 664 (1980); Steinwald & Sloan, *Regulatory Approaches to Hospital Cost Containment: A Synthesis of the Empirical Evidence*, in A NEW APPROACH TO THE ECONOMICS OF HEALTH CARE 2736 (M. Olson ed. 1981).

[59]Donabedian, *supra* note 5, at 200; Light, *Is Competition Bad?*, 309 NEW ENG. J. MED. 1315 (1984); *see also* Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs, supra* note 9, at 12-13.

[60]*See* DEP'T OF HEALTH, EDUCATION & WELFARE, MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS? (Proceedings on the 1977 Sun Valley Forum on National

structure and financing of most health insurance plans, including public programs.[61] Specifically, health insurance with low or no coinsurance insulated the consumers from any financial consequences of their decision to use health care services, resulting in indiscriminate and wasteful use of services.

Toward the end of the 1970's, recognition of these problems with the American health care system precipitated a loss of confidence in the direction of federal health policy causing many to question the underlying assumptions that had supported federal health policy for over a decade.[62] Specifically challenged was the idea that the federal government should be involved in providing health insurance for all Americans in view of the costly track record of the Medicare and Medicaid programs.[63] Also questioned was whether regulation of capital investment and institutional payment rates were effective in assuring rational distribution of health care services as well as containment of health care costs.[64] It was suggested that the new direction for federal health policy was to promote competition between providers, to reform the structure and financing of public and private health insurance programs to have consumers directly affected by their decisions to use health care services, and to reduce the regulatory control of federal and state governments over providers and health insurers.[65]

B. The Redirection of Federal Health Policy

The election of Ronald Reagan in 1980 marked the turning point in national health policy and the rejection of the liberal health policy

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Health, 1977); L. RUSSELL, *Technology in Hospitals: Medical Advances and Their Diffusion* (1979); *see also* OFFICE OF TECHNOLOGY ASSESSMENT, *Medical Technology Under Proposals to Increase Competition in Health Care* (1982).

[61] *See* P. JOSKOW, CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION 20-31, 36-43 (1981); THE ROLE OF HEALTH INSURANCE IN THE HEALTH SERVICES SECTOR (R. Rosett ed. 1976); Feldstein, *The Welfare Loss of Excess Health Insurance*, 81 J. POL. ECON. 251 (1973).

[62] *See, e.g.*, I. ILLICH, MEDICAL NEMESIS (1976); Starr, *The Politics of Therapeutic Nihilism*, in WORKING PAPERS FOR A NEW SOCIETY 48 (1976).

[63] *See* NATIONAL HEALTH INSURANCE: WHAT NOW, WHAT LATER, WHAT NEVER, *supra* note 54; *see also* Blumstein & Zukoff, *Public Choices in Health: Problems, Politics and Perspectives on Formulating National Health Policy*, 4 J. HEALTH POL. POL'Y & L. 382 (1979).

[64] C. HAVIGHURST, DEREGULATING THE HEALTH CARE INDUSTRY 25-52 (1982); P. JOSKOW, *supra* note 61, at 169-78.

[65] A. ENTHOVEN, HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE (1980); *see also Competition and Regulation in Health Care Markets*, 59 MILBANK MEMORIAL FUND Q./HEALTH AND SOCIETY 107 (1981); *A Special Symposium: Market Oriented Approaches to Achieving Health Policy Goals*, 34 VAND. L. REV. 849 (1981).

of the previous fifteen years. Ronald Reagan had a fundamentally conservative conception of government's responsibility toward its citizens and was committed to disengaging the federal government from all aspects of American life and reducing federal taxes dramatically. Thus, instead of expanding the federal role in assuring access to quality health care services to underserved groups, which had clearly been the focus of the Carter Administration's health policy,[66] the Reagan Administration sought to reduce the federal role and commitment to assure quality health care services for Americans in need and to address the problem of cost inflation in public health insurance programs. The Reagan Administration aggressively redirected federal health policy along the lines suggested by the more articulate critics of the liberal health policy such as Alan Enthoven and Clark Havighurst and even enlisted the involvement of these critics in the formulation of a new conservative health policy.

The summer of 1981 was an eventful season for American health policy. The newly-elected and politically powerful Reagan Administration under the technical leadership of the energetic Budget Director David Stockman worked feverishly to develop proposals to dismantle the liberal welfare state and to inaugurate the conservative revolution promised by the election of Ronald Reagan. The specific objective of these proposals was to reduce the amount of the nation's resources commanded by the federal government and to reduce the proportion of federal resources devoted to social programs. The Administration submitted legislative proposals affecting all aspects of American life, which Congress considered in developing the federal budget for fiscal year 1982. With respect to health, the Administration proposed transferring financial and administrative responsibility for nearly all categorical health programs to the states in block grants[67] and to impose a limit on the amount of federal expenditures for the Medicaid program while giving states greater administrative flexibility to achieve savings.[68]

But before adopting these proposals for the federal budget, Congress enacted the Economic Recovery Act of 1981, which contained the Reagan Administration's proposals for sharply reducing federal income taxes, thus reducing the proportion of the nation's resources commanded for government ends.[69] This legislation was to result in an estimated revenue

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[66]DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASS'T SECRETARY FOR PLANNING & EVALUATION, BACKGROUND PAPERS, VOL. 1 (1980); DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASS'T SECRETARY FOR PLANNING & EVALUATION, DECISION PAPERS FOR THE SECRETARY, VOL. 2 (1980).

[67]CONG. BUDGET OFFICE, AN ANALYSIS OF PRESIDENT REAGAN'S BUDGET REVISIONS FOR FISCAL YEAR 1982, STAFF WORKING PAPERS, A-53 (1981).

[68]*Id.* at A-56.

[69]Economic Recovery Act of 1981, Pub. L. No. 97-34, 95 Stat. 172.

loss of $37.7 billion for fiscal year 1982[70] despite the fact that the deficit in the federal budget at the time, fiscal year 1981, was $59.6 billion.[71] It should be noted that the actual budget deficit for fiscal year 1982 was $110.6 billion.[72] The Reagan Administration, committed to expanding the nation's defense capability through massive expenditures on national defense, sought to address the budget deficit through draconian decreases in social and health programs and, raising the specter of the increasing deficit, the Administration sought public support to dismantle the American social welfare state.[73]

The major piece of legislation to accomplish this task was the Omnibus Budget Reconciliation Act of 1981,[74] which Congress enacted immediately after the Economic Recovery Act of 1981. In this legislation, Congress adopted many of the health policy proposals and budget reduction strategies of the immensely popular Reagan Administration, including block grants for categorical social and health programs and sharp reduction in funding for regulatory programs such as federally-mandated health planning and certificate of need programs and the peer review organization program for the Medicare and Medicaid programs.[75] The Omnibus Budget Reconciliation Act also reduced federal funding for Medicaid and gave states greater flexibility to structure payment methods and modes of delivering health care services to Medicaid beneficiaries.[76]

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[70]H.R. CONF. REP. No. 215, 97th Cong., 1st Sess. 292, *reprinted in* 1981 U.S. CODE CONG. & ADMIN. NEWS 380.

[71]EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT & BUDGET, FY 1982 BUDGET REVISIONS 11 (1981).

[72]EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT, FY 1984 M-11 (1983).

[73]*See generally* D. STOCKMAN, THE TRIUMPH OF POLITICS: WHY THE REAGAN REVOLUTION FAILED (1986); Jacob, *Reaganomics: The Revolution in American Political Economy*, 48 LAW & CONTEMP. PROBS. 7(1985); *see also* Ethridge, *Reagan, Congress, and Health Spending*, 2 HEALTH AFF. 14 (1983); Michaelson, *Reagan Administration Health Legislation: The Emergence of a Hidden Agenda*, 20 HARV. J. ON LEGIS. 575 (1983).

[74]Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, 95 Stat. 357.

[75]*Id.* §§ 1901-1910, 1911, 1921-1922, 1926, 2191-2194 (codified as amended at 42 U.S.C. §§ 201-300 (1982 & Supp. 1985)).

With respect to categorical health services programs of the Public Health Service, the Omnibus Budget Reconciliation Act of 1981 terminated federal programmatic responsibility for nearly all of these programs and placed funding for these programs into block grants to be administered by states. *Id.* §§ 300w to 300w-8. Funding for these block grants was reduced by twenty-five percent in 1981 and has been reduced subsequently. *See* THE REAGAN EXPERIMENT: AN EXAMINATION OF ECONOMIC AND SOCIAL POLICIES UNDER THE REAGAN ADMINISTRATION 280-82 (J. Palmer & I. Sawhill eds. 1982). The Reagan Administration, in its new federalism initiative, proposed even greater transfers of federal responsibility for social programs to states. *See President's Federalism Initiative, Governmental Affairs, United States Senate*, 97th Cong., 2d Sess., Feb. 4, Mar. 11, 16, 18 (1982).

[76]Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, §§ 2161-2184, 95 Stat. 357 (codified as amended at 42 U.S.C. § 1396 (1982 & Supp. 1985)). *See generally* R.

What the Reagan Administration and Congress accomplished with this first wave of legislation in the summer of 1981 was to reduce the proportion of federal resources devoted to health care at the societal level. Indications are that these decisions have hurt the poor and those without health insurance. About fifteen percent of the population report having no health insurance—a significant barrier to access to health services given the high cost of even minimal medical care.[77] This figure is a twenty-five percent increase since 1977 and is due to several factors such as increased unemployment, an increase in the number of individuals living in poverty, and a tightening of criteria for Medicaid and other public programs that finance health care for the poor.[78] There is also evidence that the health status of mothers and infants and persons with chronic disease, groups likely to be poor and the beneficiaries of public programs, has been significantly compromised since 1980.[79]

After the summer of 1981, the Reagan Administration turned its attention to developing strategies to make Medicare and private insurance programs more efficient purchasers of health care services. The Administration's chief policy initiative and critically important from a rhetorical perspective was to encourage increased competition in the health care system through the reform of health insurance and, particularly, federal financing of private health insurance through the federal income tax exemption for health insurance premiums.[80]

However, the most important of these structural reforms was adoption of the prospective payment system for the Medicare program. Pressed by the need to reduce federal budget expenditures and alleviate the alarming growth of the federal budget deficit, which in fiscal year 1983

Bovbjerg & J. Holahan, Medicaid in the Reagan Era: Federal Policy and State Choices (1982); The Reagan Experiment, *supra* note 75. Congress did not adopt the Reagan Medicaid proposals because of pressure from governors who were concerned about possible increased Medicaid program costs for states. *See* Wing, *The Impact of Reagan-Era Politics on the Federal Medicaid Program*, 33 Cath. U.L. Rev. 1 (1983).

[77]*See supra* note 33 and accompanying text.

[78]Mundingher, *supra* note 12, at 45.

[79]*See id.*

[80]*See* H.R. Doc. No. 24, 98th Cong., 1st Sess. (1983); *Proposals to Stimulate Competition in the Financing and Delivery of Health Care, 1981: Hearings Before the Subcomm. on Health of the Comm. on Ways and Means of the House of Representatives*, 97th Cong., 1st Sess. (1981). Congress never enacted the Reagan Administration's competition proposal and this policy initiative, although referred to constantly in the rhetoric of the Administration, never was developed beyond an initial legislative proposal. *See Medicare Reimbursement to Competitive Medical Plans, Hearing Before the Special Comm. on Aging*, 97th Cong., 1st Sess. (1981); Congressional Budget Office, Containing Medicare Care Costs Through Market Forces (1982); Enthoven, *The Competition Strategy: Status and Prospects*, 304 N. Eng. J. Med. 109 (1981); Feder, Holahan, Bovbjerg & Hadley, *The Shift in Social Policy: Health*, in The Reagan Experiment 271 (J. Palmer and I. Sawhill eds. 1982).

was estimated to be $107.2 billion,[81] Congress and the Reagan Administration sought to address the largest component of the federal health budget where reforms were possible and which had been left relatively untouched in the initial budget cutting efforts of 1981: Medicare expenditures for hospital services. In the Tax Equity and Fiscal Responsibility Act of 1982, Congress laid the groundwork for prospective payment by establishing limits on the costs that Medicare would pay hospitals for each patient case and calling on the Department of Health and Human Services to develop a legislative proposal for a prospective payment system by December 1982.[82] Following the Administration's proposal for a prospective payment system based on diagnosis related groupings (DRG's),[83] Congress adopted a prospective payment system the following spring in the Social Security Amendments of 1983.[84]

The legislative initiatives of Congress and the Reagan Administration to purchase health care services more efficiently in the Medicare and Medicaid programs and to encourage private payers to do likewise seem to have been quite successful. In 1984, the rate of inflation in the hospital industry declined dramatically, and Medicare expenditures for hospital services rose only at 9.6% in 1984 compared to 16.7% between 1977 and 1983.[85] This result alone was significant for it defused the problem of hospital costs, which was becoming a serious economic and political problem for this nation. The problem of costs also posed a host of ethical issues of quite another dimension about the allocation of health care services, including whether resources that could be allocated to other social needs, i.e., housing, food, energy, became unavailable because of the need to purchase expensive health care services.[86]

There are indications that structural efficiencies in the delivery of health care services have occurred as well. Hospital admissions for the elderly declined for the first time since 1965, average length of stay continued to decline and data suggest that hospitals were taking care

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[81]EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT: FISCAL YEAR 1983 3-23 (1982).

[82]Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 101, 96 Stat. 331-36 (codified as amended at 42 U.S.C. § 1395ww(a)-(c) (Supp. 1985)).

[83]SECRETARY OF THE DEP'T OF HEALTH & HUMAN SERVICES, REPORT TO CONGRESS ON HOSPITAL PROSPECTIVE PAYMENT FOR MEDICARE (1982) [hereinafter HHS REPORT TO CONGRESS].

[84]Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww (Supp. 1985)).

[85]PROSPECTIVE PAYMENT ASSESSMENT COMM'N, MEDICARE PROSPECTIVE PAYMENT AND THE AMERICAN HEALTH CARE SYSTEM: REPORT TO THE CONGRESS 19-20 (1986) [hereinafter PROPAC REPORT ON THE AMERICAN HEALTH CARE SYSTEM]; *see also National Health Expenditures, 1984*, *supra* note 14.

[86]*See* P. MENTZEL, MEDICAL COSTS, MORAL CHOICES: A PHILOSOPHY OF HEALTH CARE ECONOMICS IN AMERICA (1983).

of sicker groups of patients than before.[87] Also, there was greater utilization of outpatient services in 1984 than in previous years.[88] Furthermore, all this has been accomplished while maintaining the financial position of the hospital industry. Indeed, hospitals have, as a whole, done quite well under these new strategies with profits in 1984 increasing 27.6% over 1983.[89]

The redirection of federal health policy since 1981 has precipitated concern among providers, consumers, and other observers as to whether the American health care system can continue to strive for quality and accessible health care for all Americans. Some have wondered whether constraints imposed by new payment methodologies will require the "rationing" of health care services among those in need.[90] Also many are concerned that the quality of health care services will decline because of incentives in these purchasing strategies that encourage providers to curtail the amount of services in the treatment of individual patients.[91] Also, philosophers have questioned the morality of payment systems that place providers in a position of having to balance the cost of resources used to treat patients against their anticipated benefits—particularly when the provider stands to gain personally from saving costs or is at risk for excessive costs.[92]

However, there is no evidence that this nation is now in a position where it must really "ration" health services in any draconian sense. Rather, the federal government as well as the states and private payers have decided only that they must pay less for health services. Further, as the Reagan Administration's tax and budget policies indicate, there are societal resources that could be devoted to health services for those in need. This Administration has simply decided to limit resources available to government to address such needs and look to other quarters for solutions. Thus, federal and state payers have made choices about the allocation of health services at least for vulnerable, poor groups prematurely and frankly unnecessarily.

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[87]PROPAC REPORT ON THE AMERICAN HEALTH CARE SYSTEM, *supra* note 85, at 19-20.

[88]*Id.*

[89]*Id.* at 47-51; *National Health Expenditures, 1984*, *supra* note 14, at 7-8, 23.

[90]*See, e.g.*, Friedman, *Rationing and the Identified Life*, HOSPITALS, May 16, 1984, at 65; Fuchs, *The "Rationing" of Medical Care*, 311 NEW ENG. J. MED. 1572 (1984); Perkins, *The Effects of Health Care Cost Containment on the Poor: An Overview*, 19 CLEARINGHOUSE REV. 831 (1985); Schwartz & Aaron, *Rationing Hospital Care: Lessons from Britain*, 310 NEW ENG. J. MED. 52 (1984).

[91]*See, e.g.*, Leaf, *The Doctor's Dilemma and Society's Too*, 310 NEW ENG. J. MED. 718 (1984); Omenn & Conrad, *Implications of DRG's for Clinicians*, 311 NEW ENG. J. MED. 1314 (1984); Sandrick, *Quality: Will It Make or Break Your Hospital*, HOSPITALS, July 5, 1986, at 54; Schramm, *Can We Solve the Hospital Cost Problem In Our Democracy?*, 311 NEW ENG. J. MED. 729 (1984); Thurow, *Learning to Say No*, 311 NEW ENG. J. MED. 1569 (1984).

[92]*See supra* note 6 and accompanying text.

IV. Making Hard Choices Under the Medicare Prospective Payment System

In the prospective payment system, Congress adopted a payment methodology to purchase hospital services for Medicare beneficiaries more efficiently and to curtail the amount of resources the federal government devoted to medical care for the elderly and disabled. The chief objective of this payment system was to change incentives in hospital financial behavior.[93] No longer would Medicare pay virtually all costs associated with services that hospitals and physicians decided were needed to treat individual Medicare patients. Rather, the Medicare prospective payment system pays a fixed price per case and allows hospitals to keep savings while putting hospitals at risk for costs incurred over and above the price per case.[94]

Congress understood that the prospective payment system would give the executive branch considerable power in deciding the amount of total federal resources to devote to hospital services for Medicare beneficiaries. Congress was frankly concerned that the executive branch, faced with tremendous pressure to curtail the ever increasing federal budget deficit of $107.2 billion[95] and the threatened bankruptcy of the Hospital Insurance Trust Fund,[96] would set payment rates arbitrarily low with little regard to maintaining the quality of services for Medicare beneficiaries.[97]

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[93]With respect to incentives, the House Ways and Means Committee stated, "[The Prospective Payment System] is intended to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost-effective hospital practices." H.R. Rep. No. 25, Part 1, 98th Cong., 1st Sess. 132, *reprinted in* 1983 U.S. Code Cong. & Admin. News 219, 351.

Similarly, the Administration in its report to Congress on the prospective payment system stated:

> The ultimate objective of PPS is to set a reasonable price for a known product. This provides incentives for hospitals to produce the product more efficiently. When PPS is in place, health care providers will be confronted with strong lasting incentives to restrain costs for the first time in Medicare's history.

Dep't. of Health & Human Services, Hospital Prospective Payment for Medicare: Report to Congress Required by the Tax Equity and Fiscal Responsibility Act of 1982, 101 [hereinafter HHS Report to Congress]; *see also* 20 Years of Medicare and Medicaid, Health Care (Supp. 1985) (comments of J. Alexander McMahon, at 93-94; comments of Congressman Dan Rostenkowski, at 113-14).

[94]*See infra* notes 107-25 and accompanying text.

[95]*See supra* notes 66-92 and accompanying text.

[96]Svahn & Ross, *Social Security Amendments of 1983: Legislative History and Summary of Provisions*, Soc. Security Bull., July 1983, at 3, 40-7.

[97]*See Hospital Prospective Payment System, Hearing Before the Subcomm. on Health of the Senate Comm. on Finance*, 98th Cong., 1st Sess., Part I, 47-48, 97-98, 134-35, 212 & Part II, 89-90, 162-204, 213 (1983) [hereinafter *Senate Finance Comm. Hearings on the Hospital Prospective Payment System*]; *Medicare Hospital Prospective Payment System: Hearings Before the Subcomm. on Health of the House Comm. on Ways and*

Afterall, Medicare expenditures for hospital services comprised an estimated seven percent of the federal budget for fiscal year 1983,[98] and thus posed an excellent target for budget reductions.

Hospitals were especially concerned about the administrative process by which payment rates would be set. The American Hospital Association (AHA) urged that the Secretary of HHS not have sole responsibility for updating hospital payment rates but that updating rates be done "on a regularly-scheduled basis, with the formula specified in law and calculated by a technical body that is independent of HHS and capable of providing an objective adjustment."[99] The AHA and other groups also objected to proposals eliminating rights to appeal issues with respect to the composition of hospital payment rates.[100]

Congress and beneficiaries were concerned about the incentives in the prospective payment system for hospitals to maximize payment through admitting patients to the hospital unnecessarily and encouraging their physicians to use fewer resources to treat patients.[101] Specifically, they were concerned that the quality and accessibility of hospital care for Medicare beneficiaries, particularly those who were seriously ill and had the greatest need, would be compromised.[102] With respect to quality assurance, the Senate Finance Committee and some interest groups questioned the ability of fiscal intermediaries, i.e., Blue Cross plans and insurance companies with which HHS contracts to administer Medicare coverage and payment determinations,[103] to carry out this key function, and wanted Peer Review Organizations (PRO's), with their mandated physician control, to assume this monitoring responsibility.[104]

Congress disagreed with the Reagan Administration about the appropriate administrative structure for the prospective payment system in

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Means, 98th Cong., 1st Sess. (1983) [hereinafter *House Ways and Means Comm. Hearings on Medicare Hospital Prospective Payment System*].

[98]EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT & BUDGET, BUDGET OF THE UNITED STATES, FY 1984 5-129 (1983).

This figure was derived by dividing estimated Medicare budget outlays for FY 1983 by total federal budget outlays for FY 1983.

[99]*Senate Finance Comm. Hearings on the Hospital Prospective Payment System*, *supra* note 97, Part I, at 128, 135 (statement of J. Alexander McMahon, President, American Hospital Association).

[100]*See id.* at 123-27; *House Ways and Means Comm. Hearings on Medicare Hospital Prospective Payment System*, *supra* note 97, at 19-30.

[101]*See Senate Finance Comm. Hearings on the Hospital Prospective Payment System*, *supra* note 97, Part I, 47-48, 96-98, Part II, 162-204, 213, 293-98; *House Ways and Means Comm. Hearings on Medicare Hospital Prospective Payment System*, *supra* note 97, at 123-29, 139-44.

[102]*Id.*

[103]*See* 42 U.S.C. § 1395h (1982 & Supp. 1985).

[104]*Senate Finance Comm. Hearings on the Hospital Prospective Payment System, supra* note 97, Part II, at 9-90, 162-204, 213.

several respects. The Administration had proposed that the Secretary set the hospital payment rates with input from an outside panel of experts on hospital finance appointed by the Secretary and that fiscal intermediaries monitor hospital admitting and discharge practices and the quality of care accorded Medicare beneficiaries.[105] Further, under the Administration's proposal, providers would have no right to appeal any payment issue—an approach justified as necessary to preserve the integrity of the rate structure under the prospective payment system.[106] But it is fair to say that some of the congressional distrust of the Administration's approach for structuring the prospective payment system came from a perception of this particular Administration's ideological belief that the federal government's role in addressing social problems should be minimal.

A. The Administrative Structure for Making Allocation Decisions Under the Prospective Payment System

Congress decided that decisions by the federal government at the societal level as well as by hospitals and physicians at the individual level about the allocation of medical resources under the Medicare program would be made by setting a price for each Medicare case. Specifically, through the pricing process, the federal government would make the decisions about what federal resources to devote to Medicare hospital services versus other public obligations such as defense and further, about what resources to dedicate to all public obligations versus those that should be left for private purposes. At the individual level, price would also influence how individual hospitals and physicians would decide what resources to use for the care of individual Medicare beneficiaries.

In designing the administrative structure for the prospective payment system, Congress had four chief objectives: (1) ensure that the price was fair compensation for services rendered and thus would not compromise access to hospital services particularly for the more seriously ill; (2) ensure that the process for updating the price would account for new

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[105]*Senate Finance Comm. Hearings on the Hospital Prospective Payment System*, *supra* note 97, Part I, 5-11.

[106]HHS Report to Congress, *supra* note 83, at 41. In this report, HHS stated its position on proscribing hospital appeals altogether:

> Payment amounts, exceptions, adjustments, and rules to implement the prospective payment system would not be subject to any form of judicial review. . . . As with any service sold to the Government, the remedy for providers dissatisfied with the rate offered is to convince the purchasing agency that a higher rate is appropriate or, failing that, to refrain from offering services to the Government.

Id.

medical technology, inflation, and other factors that legitimately affect the ability of hospitals to provide care; (3) monitor the quality of hospital services for Medicare beneficiaries under the prospective payment system, and (4) provide a mechanism through which beneficiaries and hospitals could resolve problems with their treatment under the system.[107]

In designing the administrative structure for the prospective payment system, Congress assigned responsibilities to organizations outside the executive branch to participate in decisions about allocation of resources at the societal level as well as at the individual level. Through the use of independent organizations in this unprecedented manner, Congress sought to create a check on the executive branch's control of the prospective payment system and to provide input from the hospital industry, the medical profession, and Medicare beneficiaries on its implementation and operation. This approach to designing an administrative structure for a public insurance program is unique and extraordinary. It provides one model for how a government health insurance program can be structured to enable the government as both payer and representative of the public to make ethical decisions in allocating societal resources to medical care for its beneficiaries and, further, to ensure that providers make fair allocation decisions with respect to individual beneficiaries.

1. The Medicare Rate Structure.—Congress gave HHS primary responsibility for setting and updating hospital payment rates.[108] In determining the rate setting methodology initially, Congress faced four central issues: (1) how would Medicare cases be classified for pricing purposes without jeopardizing the availability of services for seriously ill patients requiring above average amounts of hospital services per hospital stay; (2) what costs would be included in the prices and what costs would be reimbursed separately; (3) how would the rate structure accommodate the various missions, characteristics and geographic locations of different hospitals; and (4) how would the transition from cost reimbursement to the new payment system be accomplished.[109] Congress was also aware that precise data were not available to address these questions adequately and thus flexibility had to be incorporated into the rate setting methodology to address these questions and other unanticipated problems in the future.[110]

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[107]*See generally* H.R. Rep. No. 25, 98th Cong., 1st Sess. 132 (1983); S. Rep. No. 23, 98th Cong., 1st Sess. 111 (1983).

[108]42 U.S.C. § 1395ww(e)(5)(A) (Supp. 1985).

[109]*See Senate Finance Comm. Hearings on the Hospital Prospective Payment System, supra* note 97, at 3-11; *House Ways and Means Comm. Hearings on the Medicare Prospective Payment System, supra* note 97, at 10-13.

[110]H.R. Rep. No. 47, 98th Cong., 1st Sess. 202 (1983).

Under the prospective payment system, the Medicare program pays hospitals a fixed price for each Medicare case based on the diagnosis related grouping (DRG) in which the patient's particular condition falls.[111] The basic concept of the DRG classification system, which is comprised of 470 mutually exclusive DRG's, is that all human disease can be classified according to organ system, length of stay, intensity of resources consumed, morbidity, and sex and that such categories reflect the average cost of providing hospital services to all patients with diseases that fall within the particular category.[112]

The price is determined using a formula by which a figure representing the average price per case for all Medicare cases, called the "standardized amount," is multiplied by the DRG "weight" assigned to the particular patient's case.[113] However, if a particular case greatly exceeds the cost and length of stay ordinarily required for a case in the DRG to which the case would be assigned, Medicare will pay more for that "outlier" case than the DRG price.[114] Some costs are excluded from DRG's, including capital costs of interest and depreciation,[115] as well as the direct costs of medical education.[116]

In a transition period from fiscal year 1983 through fiscal year 1987, the standardized amount is based in part on the actual costs of individual hospitals although in following years, the standardized amount will simply be a national average cost per case for all rural and all urban hospitals.[117]

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[111]42 U.S.C. § 1395ww(d)(1) (Supp. 1985).

[112]This case classification system is based on the *International Classification of Diseases, Ninth Revision, Clinical Modification,* developed by the World Health Organization. *See* Preamble to Interim Final Rule, Medicare Program; Prospective Payments for Medicare Inpatient Hospital Services, 48 Fed. Reg. 39,752 (Sept. 2, 1983), at 39,760-61.

[113]42 U.S.C. § 1395ww(d)(1) (Supp. 1985). The DRG weight is a figure representing the proportion of hospital resources that patients in the DRG use on average compared to the average cost of all Medicare cases. *Id.* § 1395ww(d)(4)(B).

[114]*Id.* § 1395ww(d)(5).

[115]*Id.* § 1395ww(a)(4). Congress intended to incorporate capital costs in the DRG prices within a few years after the inception of the prospective payment system. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(d), 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(g)(1) (Supp. 1985)). HHS proposed taking this step for fiscal year 1987 as did the Prospective Payment Assessment Commission. *See* DEP'T OF HEALTH & HUMAN SERVICES, REPORT TO CONGRESS, HOSPITAL CAPITAL EXPENSES: A MEDICARE PAYMENT STRATEGY FOR THE FUTURE (1986); PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES [hereinafter PROPAC REPORT AND RECOMMENDATIONS TO THE SECRETARY, APRIL 1, 1986]. Congress did not take this step for fiscal year 1987 but only imposed limits on reimbursement of hospitals' capital costs for the next few years. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9303, 100 Stat. ____.

[116]42 U.S.C. § 1395ww(a)(2) (Supp. 1985). The prospective payment system also pays an additional allowance to teaching hospitals for higher costs associated with teaching activities. *Id.* § 1395ww(d)(5)(B).

[117]*Id.* §§ 1395ww(b)(3)(A), 1395ww(d)(1).

The standardized amount is updated for inflation and other factors discussed below; "standardized" to remove costs attributable to explainable differences between hospitals, i.e., area wage rates, teaching status, and case mix; and adjusted to reflect payments in outlier cases and the wage level for the area in which the hospital is located.[118]

Congress required HHS to update payments to hospitals annually. This process involves (1) adjusting the standardized amount to reflect inflation, hospital productivity, and new technology, and (2) readjusting the DRG's to reflect changes in resource consumption due to new technology and other factors.[119] In updating the standardized amount, the Secretary must take into account changes in the hospital "market basket" (i.e, the goods and services hospitals purchase to care for Medicare beneficiaries), hospital productivity, technological and scientific advances, quality of health care, and the "long term effectiveness" of the Medicare program as well as recommendations of the Prospective Payment Assessment Commission (ProPAC).[120] The Secretary, also with the advice of ProPAC, must annually adjust the DRG classification and weighting factors "to reflect changes in treatment patterns, technology and other factors which may change the relative use of hospital resources."[121]

There have been serious concerns about the fairness of the prospective payment system's rate setting methodology. First, do the DRG prices, which are based on averages, discriminate against more seriously ill patients who require more resources for their care and cause hospitals to incur costs over and above the DRG price for the patient's diagnosis?[122] Second, does the exclusion of certain costs from the DRG prices compromise the cost saving capability of the pricing system and equity between hospitals by allowing hospitals to push as much of their costs as possible into accounting categories, i.e., capital and medical education, that are reimbursed separately on a cost basis?[123] Third, are hospital payment rates and particularly the DRG prices, which are established according to older data on hospital cost experience, flexible enough to

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[118] *Id.* § 1395ww(d).

[119] *Id.* §§ 1395(d)(3)(A), (d)(2)(D).

[120] *Id.* § 1395ww(e)(2).

[121] *Id.* § 1395ww(d)(4)(C).

[122] *See* Horn, Bulkley, Sharkey, Chambers, Horn & Schramm, *Interhospital Differences in Severity of Illness: Problems for Prospective Payment Based on Diagnosis-Related Groups (DRG's)*, 313 NEW ENG. J. MED. 20 (1985); Horn, Sharkey & Bertram, *Measuring Severity of Illness: Homogeneous Case Mix Groups*, 21 MEDICAL CARE 14 (1983); *see also* AM. HOSP. ASS'N, MEDICARE PROSPECTIVE PRICE BLENDING ON A DRG-SPECIFIC RATE: A POTENTIAL MEANS OF REACHING THE MOST EQUITABLE METHOD OF DETERMINING THE MEDICARE PRICES TO BE PAID TO EACH HOSPITAL (1984).

[123] *See* Verville, *Medicare Rate Setting and Its Problems: A Fixed Price Per Bundled Product*, 6 J. LEGAL MED. 85 (1985).

permit development and diffusion of new and efficacious medical technology.[124] Finally, are hospitals with special missions and characteristics fairly treated under the prospective payment system?[125]

2. Making Decisions at the Societal Level: The Role of The Prospective Payment Assessment Commission.—Congress created ProPAC, a congressional commission, to participate in the process of setting and updating the DRG prices and essentially to evaluate the performance of the executive branch in making allocation decisions at the societal level.[126] Congress conceived of this commission as serving as "a highly knowledgeable independent panel to advise the executive and legislative branches on the Medicare reimbursement system."[127] This commission is composed of seventeen experts in health care delivery, finance, and research appointed by the Director of the congressional Office of Technology Assessment and must be representative of the health care industry with members from national organizations of physicians, hospitals, and health care equipment manufacturers as well as business, labor, and the elderly.[129]

ProPAC has two statutory responsibilities: (1) to recommend to the Secretary of HHS how to update hospital payment rates, and (2) to recommend to the Secretary necessary changes in DRG's, including the advisability of establishing new DRG's, modifying existing DRG's, or changing the relative weights of the DRG's.[129] Congress sees ProPAC's mission as extending beyond these responsibilities, as stated by the House Committee on Appropriations: "[T]he Committee believes that the primary role of the Commission lies in a broader evaluation of the impact of Public Law 98-121 [sic] on the American health care system."[130] To be sure that ProPAC has the requisite information to perform these responsibilities, Congress mandated that ProPAC would have access to all relevant information, data and research within the federal government as well as adequate funding to collect information and conduct its own research.[131]

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[124]Anderson & Steinberg, *To Buy or Not to Buy: Technology Acquisition Under Prospective Payment*, 311 NEW ENG. J. MED. 182 (1984).

[125]*See Senate Finance Comm. Hearings on the Hospital Prospective Payment System, supra* note 97, Part I, 129-46; *House Ways and Means Comm. Hearings on the Medicare Prospective Payment System, supra* note 97, at 36-44.

[126]Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(e), 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(e)(2) (Supp. 1985)).

[127]H.R. REP. No. 911, 98th Cong., 2d Sess. 140 (1984).

[128]42 U.S.C. §§ 1395ww(e)(2), (6)(A), (6)(B) (Supp. 1985).

[129]*Id.* § 1395ww(d)(4)(D), (e)(3). *See* PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, APRIL 1, 1985, at 3 (1985) [hereinafter PROPAC REPORT AND RECOMMENDATIONS TO THE SECRETARY, APRIL 1, 1985].

[130]H.R. REP. No. 911, 98th Cong., 2d Sess. 140 (1984).

[131]42 U.S.C. §§ 1395ww(e)(6)(F), (I) (Supp. 1985).

Congress also mandated a formal schedule of public communications between ProPAC and HHS with respect to the annual updating of hospital payment rates. ProPAC must prepare three reports each year: (1) a report to the Secretary on adjustments to the prospective payment system; (2) a report to Congress on the prospective payment system and the American health care system; and (3) a report to Congress on the adjustments adopted by the Secretary in his annual October regulations to govern the prospective payment system for the upcoming fiscal year.[132] The Omnibus Budget Reconciliation Act of 1986 included Congress and providers, beneficiaries, and other interested parties more directly in this dialogue with the requirements that HHS prepare documented recommendations to Congress on updating payment rates by April 1st and publish the proposed rule on payment rates no later than June 1st to allow a 60 day comment period.[133] The Secretary must publish the final rule by September 30th.[134] Through this dialogue, Congress sought to impose accountability on the executive branch in setting the hospital payment rates and to ensure that providers, beneficiaries, and other interested parties have ample opportunity over and above the informal rule making process managed by HHS to become involved in the rate setting process.

3. Making Decisions at the Individual Level: The Role of Peer Review Organizations.—To ensure that hospitals and physicians make good decisions about the allocation of hospital services at the individual level, Congress gave Peer Review Organizations important monitoring and enforcement responsibilities over hospital conduct under the prospective payment system.[135] PRO's are private, physician-controlled organizations designated under the Peer Review Improvement Act of 1982.[136] HHS contracts with PRO's to have PRO's perform certain functions and accomplish specific objectives in return for payment.[137]

For the prospective payment system, Congress has required HHS to contract with PRO's to monitor four areas of hospital behavior to assure that services to Medicare beneficiaries are medically necessary, reasonable and appropriately provided on an inpatient basis: (1) the validity of diagnostic information supplied by hospitals for payment purposes; (2) the completeness, adequacy, and quality of care provided by hospitals

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[132]*Id.* § 1395ww(d)(4)(D), (e)(3). *See* H.R. REP. No. 911, 98th Cong., 1st Sess. 140 (1984).

[133]Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9302(e)(3), 100 Stat. ____ (amending 42 U.S.C. § 1395ww(e)(3) (1982 & Supp. 1985)).

[134]42 U.S.C. § 1395ww(d)(4)(D) (Supp. 1985).

[135]42 U.S.C. § 1395cc(a)(1) (1982 & Supp. 1985).

[136]Peer Review Improvement Act of 1982, tit. I, subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, §§ 141 *et seq.*, 96 Stat. 324 (codified as amended at 42 U.S.C. § 1320c-2(b)(3)(A) (Supp. 1985)).

[137]42 U.S.C. §§ 1320c-2, 1320c-3(a) (Supp. 1985).

to Medicare beneficiaries; (3) the appropriateness of hospital admissions and discharges; and (4) the appropriateness of care in "outlier" cases in which additional Medicare payment was made.[138] As a condition of payment, all hospitals must have a contract with the designated PRO authorizing the PRO to conduct these review activities.[139]

PRO's have considerable power to force hospital compliance with HHS admission and other quality standards. They may deny payment to hospitals where abusive practices are found and, in some instances, report such practices to HHS for additional enforcement action.[140] In the Consolidated Budget Reconciliation Act of 1985, this punitive authority was expanded to permit PRO's to deny payment for specific cases in which the PRO finds that substandard care was provided to a Medicare beneficiary.[141] In addition, PRO's handle appeals of beneficiaries and hospitals regarding coverage of and, in some instances, payment for hospital services under the prospective payment system.[142]

The basic responsibility of PRO's is to see that the hospital services that the Medicare program purchases for individual beneficiaries are appropriate, necessary, and provided in the most cost effective manner. PRO's are also the means by which beneficiaries as well as hospitals can challenge Medicare coverage and payment decisions that they find unfair. Implicit in these responsibilities are two critical functions from an ethical perspective. The first function is to oversee how hospitals and physicians allocate health care resources among individual Medicare beneficiaries who need these services and specifically whether these services were of sufficient amount and quality. The second function, as explained below, is to provide a mechanism whereby individual beneficiaries can register complaints when they believe that hospitals, physicians, or the Medicare program have not allocated resources fairly in their individual cases.

4. Protecting Individual Interests: Opportunity for Appeal.—The procedures available for administrative and judicial review under the Social Security Act are a chief means for individual beneficiaries and also hospitals to raise specific objections about their treatment under the prospective payment system and to contest decisions about the allocation of Medicare services that affect them directly. Where allocation decisions affect the quality of services, tort law also offers some protection to individual beneficiaries vis-a-vis providers. The ability of hospitals and

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[138]*Id.* § 1395cc(a)(1)(F).

[139]*Id.*

[140]*Id.* §§ 1320c-3(a)(2), 1320c-5(b)(1).

[141]Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, tit. IX, § 9403, 100 Stat. 82, 200 (amending 42 U.S.C. § 1320c-3(a)(2) (1982 & Supp. 1985)).

[142]*See infra* notes 143-50 and accompanying text.

beneficiaries to challenge the composition of DRG's is specifically precluded by statute,[143] thus effectively inhibiting the ability of individual beneficiaries and hospitals to challenge effectively the allocation of resources to Medicare hospital services at the societal level.

Beneficiaries have a right to administrative and judicial review of disputes over coverage of and payment for hospital services under the Medicare program. If a beneficiary is denied coverage and payment for any inpatient hospital service, including admission or continued stay in the hospital, the beneficiary may appeal the decision to the PRO and seek reconsideration of the PRO decision by HHS.[144] If the amount involved exceeds $200, the beneficiary can obtain a hearing before an administrative law judge in the Social Security Administration and, for claims exceeding $2000, judicial review in federal district court.[145]

As noted, individual beneficiaries have the right to challenge substandard care under the common law tort system and this ability, according to some observers, provides an effective protection against substandard or insufficient care in a rationing context.[146] In this regard, a recent California decision, *Wickline v. State*,[147] in which the court recognized that a payer could be liable for negligence in cases where a provider's decision to terminate treatment was predicated on the payer's policy of limiting payment for the treatment, is important. This case suggests tort law could provide greater protection in the future by imposing liability directly on payment programs that force hospitals to deliver services more efficiently and limit needed services in specific cases as well as some protection to providers forced to make treatment decisions because of cost considerations.

Hospitals have more limited rights of appeal under the prospective payment system. Congress prohibited providers from challenging the DRG prices through administrative appeal or judicial review. Specifically, a hospital may obtain administrative or judicial review of any payment decision except the establishment of DRG's, the methodology for classifying patient discharges into DRG's, or the appropriate weighting factor

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[143] *See infra* notes 149-50 and accompanying text.

[144] 42 U.S.C. § 1320c-4 (Supp. 1985); 42 C.F.R. §§ 473.16, .40 (1986).

[145] 42 U.S.C. § 1320c-4 (1982 & Supp. 1985); 42 C.F.R. §§ 473.16, .40 (1986).

[146] Blumstein, *Rationing Medical Resources*, *supra* note 15, at 1392-99; *see also* Schuck, *Malpractice Liability and the Rationing of Care*, 59 TEX. L. REV. 1421 (1981). *But see* Rosenblatt, *Rationing "Normal" Health Care*, 59 TEX. L. REV. 1401, 1411-19 (1981). This article challenges Professor Blumstein's thesis that medical malpractice serves as an adequate check to the unfair rationing of resources on an individual basis.

[147] 183 Cal. App. 3d 661, 228 Cal. Rptr. 661 (1986), *rev. granted*, slip op. (Cal. Nov. 20, 1986). *See* Comment, *Provider Liability Under Public Law 98-21: The Medicare Prospective Payment System in Light of* Wickline v. State, 34 BUFFALO L. REV. 1011 (1985).

for DRG's.[148] Congress, like the Reagan Administration which advocated even more restrictive appellate rights for hospitals,[149] expressly precluded such review out of concern that it would jeopardize the integrity of the rate structure under the prospective payment system.[150]

B. Performance of the Model

It is still early to assess fully the efficacy of this administrative model in making decisions about the allocation of limited Medicare resources either on a societal level or an individual level. However, at this point, the fourth year of the prospective payment system, some observations about the model and its ability to meet its important resource allocation responsibilities are possible and appropriate. In assessing the performance of this model, it must be appreciated that many hospitals have done quite well under the system[151] and serious scarcities requiring difficult allocation decisions have not occurred.

To date, four issues have emerged that suggest how this administrative model is working in allocating resources for hospital services. First is the annual process of updating hospital payment rates.[152] Second is the question of whether the prospective payment system should accord special financial treatment to hospitals that serve a disproportionate number of low income and Medicare patients.[153] Third is the implementation of the peer review program and the specific problems of developing an adequate mechanism for monitoring the quality of care that hospitals provide Medicare beneficiaries.[154] Finally there is the question of how this administrative structure dealt with reported problems that Medicare beneficiaries were discharged from hospitals in a sicker condition, against their will, and with little recourse to contest such discharge decisions.[155]

1. Updating the DRG prices.—As discussed above, the federal government makes decisions at the societal level about the allocation of federal resources to hospital services for Medicare beneficiaries by setting the price that the Medicare program will pay for each Medicare case. It is clear from performance to date that the executive branch has taken

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[148]42 U.S.C. §§ 1395oo(g)(2), 1395ww(d)(7) (1982 & Supp. 1985).

[149]*See supra* note 106.

[150]H.R. REP. No. 25, PT. 1, 98th Cong., 1st Sess. 142-3 (1983); H.R. REP. No. 47, 98th Cong., 1st Sess. 202 (1983).

[151]*See* DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, FINANCIAL IMPACT OF THE PROSPECTIVE PAYMENT SYSTEM ON MEDICARE PARTICIPATING HOSPITALS - 1984 (1984); PROPAC REPORT ON THE AMERICAN HEALTH CARE SYSTEM, *supra* note 85, at 47, 52-53; *National Health Expenditures, 1984*, *supra* note 14, at 23.

[152]*See infra* notes 156-75 and accompanying text.

[153]*See infra* notes 176-97 and accompanying text.

[154]*See infra* notes 198-208 and accompanying text.

[155]*See infra* notes 209-16 and accompanying text.

a strict view of the federal resources that will be allocated to this purpose. This position has generated conflict with hospitals and also with Congress. HHS has not adopted ProPAC recommendations on various methodologies for updating hospital payment rates and has always developed lower rates than it would using formulas suggested by ProPAC.[156] In recent years, Congress, relying on ProPAC's analysis, has legislatively supplanted HHS rules on updating hospital payment rates in order to establish more generous payment rates.[157]

In its first recommendations for fiscal year 1986 payment rates, ProPAC conservatively confined its recommendations to updating hospital payment rates and changing one DRG which had permitted hospitals to make enormous profits.[158] HHS adopted another method for updating payment rates, which resulted in a lower payment rate for fiscal year 1986, and changed several DRG's.[159] In its fiscal year 1987 recommendations, ProPAC was more activist. Besides recommendations on updating payment rates, ProPAC proposed that the Secretary include capital costs in the DRG prices beginning in fiscal year 1987 and that HHS adjust certain DRG's to reflect new treatment modalities and their use of labor resources.[160] ProPAC also addressed issues outside its strict statutory mandate and made recommendations for improved appeals procedures for beneficiaries and improved quality of care review by PRO's.[161] Again, HHS disregarded ProPAC's recommendations on hospital payment rates and adopted formulas and assumptions for fiscal year 1987 that resulted in lower payment rates than suggested by ProPAC.[162] HHS also proposed folding capital costs into the DRG prices but in a manner different and less expensively than ProPAC had proposed.[163]

The Administration's action on updating hospital payment rates for fiscal years 1986 and 1987 has been controversial. In commenting on the fiscal year 1987 rates, hospitals charged that HHS was motivated chiefly by its desire to cut Medicare budgetary expenditures rather than setting a fair price for hospital services. Specifically, according to an AHA spokesman:

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[156]*See infra* notes 165-67 and accompanying text.

[157]*See infra* notes 172-75 and accompanying text.

[158]ProPAC Report and Recommendations to the Secretary, April 1, 1985, *supra* note 129, at 8, 33-35, 41-42.

[159]Preamble to Proposed Rule, 50 Fed. Reg. 24,366. (1985); Interim Final Rule, 51 Fed. Reg. 16,772 (1986).

[160]ProPAC Report and Recommendations to the Secretary, April 1, 1986, *supra* note 115, at 32-33.

[161]*See infra* notes 209-30 and accompanying text.

[162]51 Fed. Reg. 16,772 (1986).

[163]51 Fed. Reg. 19,970, 19,983-85 (1986).

> In our response to the FFY 1986 proposed rule on PPS, AHA commented that "the Health Care Financing Administration (HCFA) has an obligation to the public to do more in the Notice than provide a statement of those beliefs that form the basis for the rule; HCFA must provide evidence which validates their beliefs." For a second year, the notice of proposed rates fails to document the appropriateness and validity of the update factor and other changes. Absent detailed evidence, AHA must assume that the primary motivating factor in the development of each component of the rate calculation is budget reduction. We can only conclude that HCFA is not truly interested in the adequacy of the rates that are promulgated, the equity of payments to hospitals or the administration of the Medicare program in a manner that reflects its responsibilities to Medicare beneficiaries and providers. If these issues had been considered in the development of the PPS rates for FY 1987, the update factor and other modifications identified by HCFA would be better documented by quantitative and qualitative evidence of the adjustments and their appropriate levels.[164]

ProPAC has also voiced complaints about HHS' conduct in updating hospital payment rates. In its comments to the proposed rule on payment rates for fiscal year 1987, ProPAC observed that its approach and that of HHS in updating hospital payment rates were "diverging in significant ways" and this divergence appeared to be based on a "difference in philosophy between the Commission and the Department."[165] ProPAC explained this difference in philosophy as based on ProPAC's belief that the prospective payment system "should be a flexible and evolutionary system responsive to changing health technology and practice patterns and to the distributional impacts of payments within the system" and that adjustments in the system are "critical to maintaining an environment which fosters innovation and scientific advancement."[166] HHS, in relying on averaging methodologies and ignoring adjustments in the payment system to reflect special circumstances and new developments in medical technology and their impact on specific DRG's, did not advance these

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[164]Letter from Jack Owen, Executive Vice President of the American Hospital Association, to William Roper, M.D., Administrator of the Health Care Financing Administration (July 3, 1986) (comments on Proposed PPS Rules for FFY 1987).

[165]Letter from Stuart H. Altman, Ph.D., Chairman of the Prospective Payment Assessment Commission, to William L. Roper, M.D., Administrator of the Health Care Financing Administration (July 2, 1986) (comments of the Prospective Payment Assessment Commission on the Notice of Proposed Rulemaking of June 3, 1986, Concerning Fiscal Year 1987 Changes in the Inpatient Hospital Prospective Payment System).

[166]*Id.*

objectives. ProPAC commented further on HHS' response to ProPAC's recommendations:

> ProPAC was established by the Congress to provide independent advice and oversight on a new, untried prospective payment system. From the beginning, we have strived to make our decision-making analytically based, with careful consideration to a wide range of options on every topic which we review. We do not believe that the Secretary's response to our recommendations always gives full consideration to the detail and extent of the problems we have identified. We also do not believe that the response exhibits the flexibility which we believe is necessary to update and maintain the system. In order to encourage the confidence of beneficiaries, providers, suppliers, and taxpayers, we hope that the Secretary will reconsider the details of our analysis in developing the final fiscal year 1987 PPS regulations.[167]

Finally, there was even debate within the Administration about the fairness of the updated payment rates, i.e., 0.5%, that the Administration had proposed in June 1986.[168] In August 1986, the new physician Secretary of HHS, Dr. Otis Bowen, took the position that if the fiscal year 1987 hospital payment rates were not updated at least 1.5%, then the quality of hospital care for Medicare beneficiaries would be jeopardized.[169] Eventually, the Office of Management and Budget prevailed in the internicine debate, and the final rule updated fiscal year 1987 payment rates 0.5%.[170]

In the context of setting the federal budget, Congress has taken an extraordinarily active role in updating hospital payment rates and thus in making allocation decisions as to how much federal resources should be devoted to hospital care for Medicare beneficiaries. Initially, Congress took a restrictive perspective as to the amount of resources to devote to this purpose and in the Deficit Reduction Act of 1984 tightened the formula for updating hospital payment rates to account for inflation.[171]

But since 1984, Congress has taken a more expansive perspective, at least when compared with the executive branch. Congress has not approved of the Administration's positions on how to adjust hospital payment rates and has supplanted HHS rules for updating hospital payment rates with legislation for fiscal years 1986 and 1987. Specifically,

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[167] *Id.*

[168] 51 Fed. Reg. 19,970 (1986).

[169] AM HOSP. ASS'N, WASHINGTON MEMO, (Memo #616, Aug. 29, 1986).

[170] 51 Fed. Reg. 31,498 (1986).

[171] Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2310(a), 98 Stat. 1075 (codified as amended at 42 U.S.C. § 1395ww(b)(3)(B) (Supp. 1985)).

Congress refused to uphold a freeze on hospital payment rates that HHS proposed for fiscal year 1986.[172] Also, in the Balanced Budget Budget and Emergency Deficit Control Act of 1985 (Graham-Rudman-Hollings), Congress mandated that hospital payments could only be reduced from fiscal year 1986 payment rates by one percent for the remainder of the fiscal year and by two percent in following years to assure that the Medicare program was not the target of excessive budget cutting.[173] Also, in the Omnibus Budget Reconciliation Act of 1986, Congress increased hospital payment rates by 1.15% for fiscal year 1987 compared to the 0.5% proposed by HHS.[174] The House Ways and Means Committee expressed considerable displeasure with HHS' performance in updating rates and the consequent need for Congress to step in and change rates legislatively, stating:

> The Committee has given, in the past, a significant amount of discretion to the Secretary of Health and Human Services in developing the annual update factor for hospital payments under the [M]edicare program. The statutory language requires that hospital payments reflect the amounts necessary for the efficient delivery of medically appropriate and necessary care of high quality.
>
> The Committee has, however, for the last two years overridden the Administration's recommended update factor. The Committee finds itself in the same situation once again this year as it finds the Secretary's recommended FY 1987 update factor unacceptable. The Committee concludes that the Administration, in developing the update factor for fiscal year 1987 used factors other than those originally anticipated in the legislation.[175]

It is clear that under the current administrative model, the executive branch has considerable authority to determine the proportion of federal resources that will be attributed to hospital care of Medicare beneficiaries. It is also clear that ProPAC's role and the mandated dialogue between

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[172]*See* Emergency Extension Act of 1985, Pub. L. No. 99-107, § 5(c), 99 Stat. 480, *amended by* Pub. L. No. 99-201, § 34, 99 Stat. 1184 (1985); Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9101, 100 Stat. 82 (codified as amended at 42 U.S.C. §§ 1395ww(b)(3)(B), (d)(3)(A) (Supp. 1985)).

This legislation abrogated the freeze on fiscal year 1986 payment rates HHS promulgated in its Final Rule of 1986 Rates, 50 Fed. Reg. 35,646 (1985), and substituted a freeze on payment rates at levels Congress determined.

[173]Balanced Budget and Emergency Deficit Control Act of 1985, Pub. L. No. 99-177, § 3256(d)(1), 99 Stat. 1087.

[174]Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9303(a), 100 Stat. ____ (amending 42 U.S.C. § 1395ww (1982 & Supp. 1985)).

[175]H.R. Rep. No. 727, 99th Cong., 2d Sess. 427 (1986).

HHS and ProPAC have not functioned as intended to force HHS to state the rationale for its decisions about payment rates in a detailed manner and justify those that are contrary to the outside commission of experts. Indeed, this process has had little effect on influencing how HHS actually updates the DRG prices. This situation has precipitated a more interventionist role by Congress in the rate setting process and has changed the role of ProPAC. ProPAC has provided Congress with the information that it needs to substitute its own judgments for those of the executive branch in this complex, highly technical area, through the political process. This administrative model thus exemplifies a process by which the legislative branch can obtain the requisite technical information to make informed judgments that are generally left to administrative agencies and their technical expertise.

2. Treatment of Disproportionate Share Hospitals.—In the prospective payment system, Congress authorized the Secretary to make exceptions and adjustment for "public and other hospitals that served a significant disproportionate number" of low income and Medicare patients.[176] In authorizing this adjustment, Congress was concerned that such hospitals may serve patients that are "more severely ill than average and the DRG payment system would not adequately take into account such factors."[177] In refining the payment methodology for the prospective payment system initially, HHS refused to adopt an adjustment for such hospitals because "current data do not show that such an adjustment is warranted," and HHS has consistently maintained this position ever since.[178]

HHS' refusal to create an adjustment for so-called disproportionate share hospitals generated considerable litigation by public and other hospitals that serve primarily low income patients seeking a judicial mandate that HHS create an exception for disproportionate share hospitals.[179] In *Redbud Hospital District v. Heckler*,[180] the United States

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[176]42 U.S.C. § 1395ww(d)(5)(c)(i) (Supp. 1985).

[177]H.R. REP. No. 25 Part I, 98th Cong., 1st Sess. 192-3 (1983); *see also* S. REP. No. 23, 98th Cong., 1st Sess. (1983); H.R. REP. No. 47, 98th Cong., 1st Sess. (1983).

[178]Preamble to Final Rule, 49 Fed. Reg. 234, 276 (1984).

[179]*See, e.g.*, Samaritan Health Center v. Heckler, [1986-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,862 (D.D.C. Aug. 28, 1985); Sunshine Health Sys., Inc. v. Heckler, [1986-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,858 (C.D. Cal. July 22, 1985); Redbud Hosp. Dist. v. Heckler, [1984-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,085 (N.D. Cal. July 30, 1984), *modified*, [1985 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,669 (N.D. Cal. June 14, 1985), *application for stay of preliminary injunction granted*, 106 S. Ct. 1 (1985) (Rehnquist, J. sitting as Circuit Judge).

[180][1984-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,085 (N.D. Cal. 1984), *modified*, [1985 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,669 (N.D. Cal. June 14, 1985), *application for stay of preliminary injunction granted*, 106 S. Ct. 1 (1985) (Rehnquist, J., sitting as Circuit Judge).

District Court for the Northern District of California ruled that the Secretary of HHS had abused her discretion in not addressing the special needs of disproportionate share hospitals and ordered HHS to promulgate regulations or written policies that would "take into account the special needs" of disproportionate share hospitals.[181] HHS did issue regulations authorizing a very narrowly drawn exception applicable for very few hospitals[182] when the *Redbud* district court ordered their promulgation by July 1, 1985.[183] HHS rescinded these regulations when Justice Rehnquist, sitting as circuit judge, stayed the court's order.[184]

Concerns about treatment of disproportionate share hospitals under the prospective payment system were raised in other arenas as well. Congress became concerned about HHS' refusal to address adequately the special needs of disproportionate share hospitals.[185] In the Deficit Reduction Act of 1984, Congress provided that before December 31, 1984, the Secretary "shall" develop and publish a definition of disproportionate share hospitals, identify those which meet the definition, and notify the Senate Finance Committee and House Ways and Means Committee accordingly.[186]

HHS did not meet this deadline and, through its inaction, behaved in a fashion that suggested that it did not plan to comply with this congressional directive. Consequently, in *Samaritan Health Center v. Heckler*,[187] the United States District Court for the District of Columbia ordered the Secretary to comply with section 2315(h) of the Deficit Reduction Act of 1984 by December 31, 1985. However, the *Samaritan Health Center* court concluded that the Secretary did have discretion as to whether or not to create an adjustment for disproportionate share hospitals.[188]

In its report to the Secretary on the fiscal year 1986 hospital payment rates, ProPAC recommended that the Secretary develop a methodology for adjusting payment rates for hospitals that serve a disproportionate share of Medicare and low income patients that Congress authorized in the Social Security Amendments of 1983.[189] ProPAC justified this rec-

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[181]*Id.* at 9884.

[182]50 Fed. Reg. 27,208 (July 1, 1985).

[183][1985 Transfer Binder] Medicare & Medicaid Guide (CCH), at ¶ 34,669.

[184]106 S. Ct. 1 (1985). *See* 50 Fed. Reg. 30,944 (July 31, 1985).

[185]*See Administration's Fiscal Year 1985 Budget Proposals: Hearings Before the Senate Comm. on Finance*, 98th Cong., 2d Sess. (1984).

[186]Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2315(h), 98 Stat. 1075 (codified as amended at 42 U.S.C. § 1395ww(b)(3)(B) (Supp. 1985)).

[187][1986-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,862 (D.D.C. Aug. 29, 1985).

[188]*Id*; *accord* Sunshine Health Sys. v. Heckler, [1986-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,858 (C.D. Cal. July 22, 1985).

[189]ProPAC Report and Recommendations to the Secretary, April 1, 1985, *supra* note 129, at 37.

ommendation with analysis of data indicating that public and other hospitals serving the poor and Medicare patients incurred greater costs in the treatment of these patients.[190] However, in its payment rates for fiscal year 1986, HHS refused to create an adjustment to reflect higher costs for disproportionate share hospitals, relying on its consistent position that HHS data did not justify such an exception.[191]

In December 1985, HHS published a definition of disproportionate share hospitals that provided that eligible hospitals must serve 39.55% low income patients and 91.01% Medicare patients.[192] According to this definition, only 108 hospitals fit under the definition, and large public hospitals that one would expect Congress intended to assist with the disproportionate share provisions were not included.[193]

ProPAC clearly was not convinced that this definition was adequate and, in its recommendations for fiscal year 1987 payment rates, ProPAC reiterated its recommendation that the Secretary implement an adjustment for disproportionate share hospitals.[194] In the proposed rule, HHS responded to ProPAC's recommendations by stating that it had complied with the Deficit Reduction Act of 1984.[195] Nor was Congress convinced that HHS had complied with its requirements that hospitals serving these special patients be treated specially and therefore fairly under the prospective payment system. In the Consolidated Budget Reconciliation Act of 1985, Congress redefined disproportionate share hospitals more generously to include more hospitals, including those urban public hospitals that one would expect would care for large proportions of indigent patients on public health insurance programs.[196] In the Omnibus Budget Reconciliation Act of 1986, Congress further refined the methodology for paying disproportionate share hospitals to provide additional assistance to those in rural areas.[197]

HHS' treatment of the disproportionate share hospital issue indicates that the executive branch has narrowly viewed the needs of hospitals serving underserved groups and restricted the allocation of Medicare resources to those hospitals. Further, it is clear that ProPAC disagrees with HHS' allocation decisions but is relatively powerless, except by

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[190]*Id.* at 37-38.

[191]50 Fed. Reg. 24,393 (1985).

[192]50 Fed. Reg. 53,398 (1985).

[193]For a list of disproportionate share hospitals, see [1986-1] Medicare & Medicaid Guide (CCH) ¶ 35,102.

[194]ProPAC Report and Recommendations to the Secretary, April 1, 1986, *supra* note 115, at 37.

[195]51 Fed. Reg. 19,970, 19,996 (1986).

[196]Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, §105, 100 Stat. 82 (amending 42 U.S.C. § 1395ww(d)(5) (Supp. 1985)).

[197]Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9306, 100 Stat. ____ (amending 42 U.S.C. § 1395ww(d)(5)(F) (Supp. 1985)).

virtue of is analytical authority, to get HHS to change its position. The key player in this allocation decision, as clearly conceived by the courts, is Congress. Congress has stepped in several times to address the problems of hospitals serving a poor clientele with special and expensive needs, indicating that the ultimate means of resolving allocation problems under the prospective payment system has been essentially political.

3. Implementation of the PRO Program.—Reviews of PRO performance in monitoring hospital behavior and quality of care under the prospective payment system are mixed. By statute, hospitals had to have a contract with a PRO by October 1984, although this date was extended to November 1984 because of HHS' delays in entering contracts with PRO's in all states and in issuing the requisite regulations for the selection and designation of PRO's and other administrative matters, a matter of grave concern to Congress.[198] By November 1984, HHS entered contracts with fifty-four PRO's for all states and territories.[199] Many PRO's were slow getting started and the performance of some PRO's was so deficient that HHS terminated their participation in the program.[200]

The chief complaint of PRO's, Congress, hospitals and beneficiaries about HHS's administration of the program in its first two years was that the contracts required PRO's to focus excessively on cost containment goals to the detriment of quality of care goals, with concentration chiefly on reducing unnecessary hospital admissions.[201] For the first PRO contracts, HHS delineated five quality objectives: (1) reduce unnecessary hospital readmissions resulting from substandard care; (2) assure provision of medical services which, if not performed, have a significant potential for causing complications; (3) reduce "avoidable deaths;" (4) reduce unnecessary surgery and invasive procedures; and (5) reduce postoperative and other complications.[202]

In the first year of the prospective payment program, concerns were raised that these objectives did not permit PRO's to determine whether

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[198]Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2347(c), 98 Stat. 494 (amending 42 U.S.C. § 1302c-2(b)(2) (Supp. 1985)). HCFA did not promulgate final regulations to govern PRO activities until April 1985. 50 Fed. Reg. 15,312 (1985).

[199]Dans, Weiner & Otter, *Peer Review Organizations—Promises and Pitfalls*, 313 NEW ENG. J. MED. 1131 (1985).

[200]*See* PROSPECTIVE PAYMENT ASSESSMENT COMM'N, TECHNICAL APPENDIXES TO THE REPORT AND RECOMMENDATIONS TO THE SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, APRIL 1, 1986, App. C at 158 [hereinafter TECHNICAL APPENDIXES TO THE PROPAC REPORT AND RECOMMENDATION TO THE SECRETARY, APRIL 1, 1986].

[201]AM. ASS'N OF PEER REVIEW ASS'NS, PRO'S: THE FUTURE AGENDA (1985); *see also* Dans, Weiner & Otter, *supra* note 200; Gosfield, *Hospital Utilization Control by PROs: A Guide Through the Maze*, HEALTH SPAN, Feb. 1984, at 3.

[202]Request for Proposal (RFP No. HCFA-84-015, Feb. 29, 1984), 48 Fed. Reg. 39,160 (1983). For each of these general objectives, PRO's must select one procedure to monitor and state numerical goals for each objective.

hospitals were providing high quality services under the prospective payment system.[203] At the same time, the General Accounting Office released preliminary data that Medicare beneficiaries were being released "quicker and sicker" and often with inadequate arrangements for post-hospital care.[204] The House Select Committee on Aging held hearings which confirmed these findings.[205]

The staff of the Senate Special Committee on Aging conducted an investigation of PRO monitoring activities and found serious deficiencies.[206] The committee staff recommended that the Secretary emphasize quality assurance in the new PRO contracts and specifically that PRO's be given power to deny payment for substandard care and that PRO's review what happens to patients after discharge from the hospital.[207] In September 1985, the Senate Special Committee on Aging held hearings on the impact of the prospective payment system on the quality of care for Medicare beneficiaries revealing significant beneficiary and provider dissatisfaction with quality of care and the failure of PRO's to detect these quality problems.[208]

In 1986, ProPAC became increasingly concerned about assuring the quality of care under the prospective payment system and ascertaining ways to determine whether quality of care was affected by the new payment rates. ProPAC was disturbed about the problem of hospitals discharging patients prematurely and without adequate arrangements for post-hospital care and about the inability of PRO's to monitor this problem sufficiently under their current contracts with HCFA.[209] ProPAC recommended that PRO quality of care review look at what happens to patients after discharge from the hospital and also at the quality of outpatient surgery provided Medicare beneficiaries. HHS was responsive to these proposals.[210]

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[203] *Quality of Care Under Medicare's Prospective Payment System: Hearings Before the Senate Special Comm. on Aging*, 99th Cong., 1st Sess. (1985) [hereinafter *Senate Special Comm. on Aging Hearings on Quality of Care*]. Government Accounting Office, *Information Requirements for Evaluating the Impacts of Medicare Prospective Payment on Post-Hospital Long-Term-Care Services: Preliminary Report* (PEMD-85-8, Feb. 21, 1985); TECHNICAL APPENDIXES TO THE PROPAC REPORT AND RECOMMENDATIONS TO THE SECRETARY, APRIL 1, 1986, *supra* note 201, at 149-50.

[204] Government Accounting Office, *supra* note 203.

[205] *See Quality of Care Under Medicare's Prospective Payment System: Hearings Before the House Select Comm. on Aging and the Task Force on the Rural Elderly*, 99th Cong., 1st Sess. (1985) [hereinafter *House Select Comm. on Aging Hearings on Quality of Care*].

[206] STAFF OF SENATE COMM. ON AGING, IMPACT OF MEDICARE'S PROSPECTIVE PAYMENT SYSTEM ON THE QUALITY OF CARE RECEIVED BY MEDICARE BENEFICIARIES (1985).

[207] *Id.* at 3.

[208] *Senate Special Comm. on Aging Hearings on Quality of Care*, *supra* note 203.

[209] *Id. See* TECHNICAL APPENDIXES TO THE PROPAC REPORT AND RECOMMENDATIONS TO THE SECRETARY, APRIL 1, 1986, *supra* note 201, App. C at 159.

[210] PROPAC REPORT AND RECOMMENDATIONS TO THE SECRETARY, APRIL 1, 1986, *supra*

As a result of these concerns, the Secretary and Congress instituted substantial changes in the quality of care review procedures for PRO's. In the new PRO contracts issued in January 1986, HCFA changed the procedures and objectives of the quality of care reviews substantially. Specifically, HCFA focused PRO review on reduction of adverse outcomes in five areas: (1) adequacy of discharge planning; (2) deaths; (3) nosocomial infections; (4) unscheduled returns to surgery for the same condition as the previous surgery or to correct post-operative problems; and (5) trauma suffered in the hospital.[211] Also, in the Consolidated Omnibus Budget Reconciliation Act of 1985, Congress gave PRO's the authority to deny payment for substandard care identified through criteria developed by HCFA.[212] Congress also imposed additional responsibilities on PRO's to review outpatient and other surgery procedures.[213]

Congress continued to be concerned about the quality of care under the Medicare prospective payment system and the role of PRO's in assuring quality of care. In the Omnibus Budget Reconciliation Act of 1986, Congress assigned important new responsibilities to PRO's. Specifically, Congress required that PRO's devote a greater proportion of their time and resources to reviewing quality of hospital services to Medicare beneficiaries and that quality of care reviews include what happens to patients after discharge from the hospital.[214] In addition, Congress required PRO's to review so-called early readmission cases to determine if previous inpatient hospital services and post-hospital services met professionally recognized standards of health care.[215] Congress has also required PRO's to have consumer representation on their boards.[216]

Whether PRO quality of care review will be improved with the reforms instituted in the new PRO contracts or the recent legislation is uncertain. Furthermore, the hospital industry has successfully challenged

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note 115. HCFA explained PRO responsibilities with respect to monitoring quality of care aspects of inpatient medical review. 51 Fed. Reg. 19,970, 19,998 (1986). This review would include criteria to detect premature discharges and review of discharge planning to determine if the availability of needed post-discharge care was considered. Regarding outpatient surgery, HCFA reported that it was in the process of developing a list of procedures for which PRO review was required, including review for outpatient procedures in light of new requirements for PRO review of surgery in the Consolidated Omnibus Budget Reconciliation Act of 1985. *Id.* at 19,998-99.

[211]The Health Care Financing Administration submitted a separate Request for Proposal to each state PRO.

[212]Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, tit. IX, § 9403, 100 Stat. 82 (amending 42 U.S.C. § 1320c-3(a)(2) (1982 & Supp. 1985)).

[213]*Id.* § 9401.

[214]Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9353(a), 100 Stat. ____ (amending 42 U.S.C. § 1320c-3(a)(4) (1982 & Supp. 1985)).

[215]*Id.* § 9352 (amending 42 U.S.C. § 1320c-2 (1982 & Supp. 1985)).

[216]*Id.* § 9353(b) (amending 42 U.S.C. § 1320c-1 (1982 & Supp. 1985)).

the process HHS used to implement the PRO program. In *American Hospital Association v. Bowen*,[217] the United States District Court for the District of Columbia ruled that HHS had improperly implemented the PRO program through program directives rather than rules properly promulgated under the the informal rule-making procedures of section 553 of the Administrative Procedure Act[218] and consequently were invalid.[219] This decision, now on appeal before the United States Court of Appeals for the District of Columbia Circuit, has generated considerable uncertainty for the PRO program, the full implications of which have yet to be determined.

Given the slow start up of the PRO program and the controversy over what PRO's are to accomplish in their reviews, it is still unclear how effective PRO's have been in assuring the adequacy of allocation of Medicare resources among Medicare beneficiaries on an individual basis. However, excessive emphasis on cost containment objectives has inhibited PRO's from monitoring thoroughly the allocation of medical resources on a individual basis.[220] Congress has demonstrated strong support and confidence in the peer review concept as a means of monitoring resource allocation and has acted aggressively on several occasions to strengthen the role of PRO's to be sure that they can function more effectively.

4. Preventing Premature Discharge from Hospitals.—The most important ethical issue regarding allocation of hospital services under the prospective payment system to emerge to date has been the premature discharge of Medicare beneficiaries from hospitals. This issue surfaced in congressional hearings and investigations in 1985 which reported problems with hospitals discharging Medicare patients against their will, early, and inappropriately with the explanation to the beneficiary that the number of covered days for the patient's illness had "run out."[221] Beneficiaries did not appeal such decisions because they were unaware of appeal procedures and, until recently, were financially liable for the continued stay.[222] This problem generated considerable publicity partic-

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[217]640 F. Supp. 453 (D.D.C. 1986); *see* Duffy, *PRO-Court Grants Secretary's Motion for Stay*, HEALTH LAW VIGIL, Oct. 10, 1986, at 4.

[218]5 U.S.C. § 553 (1982 & Supp. 1985).

[219]640 F. Supp. at 463.

[220]See Veatch, *supra* note 6, for a discussion of the ethical implications for peer review when charged with cost containment goals.

[221]*See Senate Special Comm. on Aging Hearings on Quality of Care*, *supra* note 203; *House Select Comm. on Aging Hearings on Quality of Care*, *supra* note 205; Government Accounting Office, *supra* note 203.

[222]Wilson, *How to Appeal Medicare Coverage Denials Under the DRG System*, 20 CLEARINGHOUSE REV. 434 (1986).

ularly when the elderly reporter, Sarah McClendon, opened a January 1986 presidential press conference with an unexpected question to President Reagan about this problem.[223]

Congress, ProPAC, and HHS took immediate steps to address this problem. ProPAC urged the Secretary to require hospitals to give beneficiaries immediate notice of appeal rights upon admission and to improve the information available to beneficiaries about their rights under the prospective payment system.[224] ProPAC also conducted a study which suggested that this problem was not widespread.[225] Working with consumer groups, HHS developed a notice to be given to all Medicare patients upon admission to the hospital, that would clearly explain the patient's rights to appeal any decision by the hospital, the patient's physician, or the PRO about the patient's admission or continued stay.[226]

It is not at all clear that this problem has been resolved or that it is not widespread. Both the American Medical Association and the American Society of Internal Medicine have conducted surveys of their membership. These surveys report that many patients are discharged sooner and often without adequate post-hospital placement, thus compromising the quality of medicare care for Medicare beneficiaries.[227] Consumers are also concerned about the PRO's ability to handle appeals regarding inappropriate discharge in a fair and expeditious manner.[228]

In the Omnibus Budget Reconciliation Act of 1986, Congress affirmatively addressed this problem. Specifically, it required PRO's to review all cases in which a hospital determines that a beneficiary no longer needs hospital care and the attending physician does not agree with the decision.[229] Further, Congress has required that beneficiaries have the opportunity for immediate appeal to the PRO of any discharge decision and suspended the beneficiary's financial liability for continued care during the appellate period, a critical factor in assuring that these appeal rights of appeal are meaningful.[230]

The premature discharge of Medicare beneficiaries often against their

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[223]Rovner, *Medicare: The Cost of Cost-Cutting*, Washington Post Health, Jan. 15, 1985, at 9.

[224]ProPAC Report and Recommendations to the Secretary, April 1, 1986, *supra* note 115, at 43-44.

[225]Technical Appendixes to the ProPAC Report and Recommendations to the Secretary, April 1, 1986, *supra* note 200, at 147-55.

[226]51 Fed. Reg. 19,970, 19,998 (1986).

[227]Am. Medical Ass'n, Report of the American Medical Association Board of Trustees: AMA's DRG Monitoring Project and the Prospective Payment System (1986); Am. Soc'y of Internal Medicine, The Impact of DRG's on Patient Care: A Survey by the American Society of Internal Medicine, March 1984 - October 1985 (1986).

[228]Wilson, *supra* note 222.

[229]Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9351(a), 100 Stat. ____ (amending 42 U.S.C. § 1320c-3 (1982 & Supp. 1985)).

[230]*Id.*

will and without adequate provision for post-hospital care confirms the concern that payment reforms for public or private health insurance programs designed to encourage providers to limit resources in the treatment of patients can have untoward effects. It also emphasizes the need to have an accessible process in place which allows individual beneficiaries to appeal allocation decisions that they believe are unfair.

C. Some Conclusions

The report card on the performance of this administrative model of the Medicare prospective payment system in making hard choices about the amount and allocation of medical resources is incomplete. In making decisions at the societal level, three key actors have played dominant and conflicting roles which have tested this model considerably: the executive branch, Congress, and ProPAC. The executive branch has consistently taken an extraordinarily strict position on the amount of federal resources to allocate to hospital care for Medicare beneficiaries. This strictness is amply demonstrated in the executive branch's conduct in updating hospital payment rates since the first year of the prospective payment system, as well as in its treatment of hospitals that serve a disproportionate number of low income and Medicare patients. Furthermore, the other key players, Congress and ProPAC, have not agreed with the executive branch's positions on these issues.

ProPAC has demonstrated professional expertise in its analytic work on updating the hospital payment rates and modifying the DRG's as well as in its response to issues such as ensuring quality of care, treatment of disproportionate share hospitals, and the premature discharge of beneficiaries from hospitals. ProPAC's role and function as well as the excellence of its analysis have enabled Congress to participate substantively in the rate setting process and thus to exercise greater political control over the rate setting process. In fact, this interchange with Congress has been the most important characteristic of ProPAC's role under the prospective payment system. The fact that the executive branch is not compelled to follow ProPAC's technical recommendations has proven relatively immaterial given the more generous disposition of Congress regarding decisions on allocating federal resources to the hospital care of Medicare beneficiaries. It is worth pondering, however, whether this model for making allocative decisions would operate effectively to ensure that ethical decisions are made, if Congress and ProPAC took the same strict position on rate setting issues as the executive branch. This question is especially important in view of the fact that the model has expressly limited hospitals' access to the courts to contest unfairness of some aspects of Medicare payment rates.[231]

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[231] *See supra* notes 148-50 and accompanying text.

There still remain questions about the performance of PRO's in monitoring quality of care under the prospective payment system and ensuring that proper allocation decisions are made at the individual level. Admittedly, the PRO program, which involves over 50 PRO's and nearly 5,800 hospitals,[232] is administratively complex and thus full implementation of the program will take time. But problems extend beyond mere start-up complications and are generated in large part by HHS' stewardship of the program. HHS controls the PRO monitoring process directly through its contracts and sets the agenda for the PRO reviews. Clearly, HHS has not focused PRO reviews on monitoring quality of care but rather on cost containment.

The problem of premature discharge of beneficiaries from hospitals and associated complaints suggest that many beneficiaries perceive that the federal government, through the prospective payment system, and hospitals and physicians operating under the system have made some unfair decisions about the allocation of Medicare resources among Medicare beneficiaries. This finding is curious since hospitals have done well financially under the prospective payment system.[233] It may be that some hospitals, as decision makers in the allocation of medical resources under their control, are making unnecessarily hard choices with respect to those beneficiaries in the unethical fashion anticipated by some observers. It may also be that elderly beneficiaries, accustomed to the patterns of utilization under more generous payment methodologies, perceive that needed medical services are being denied when in fact they are being provided in a different and more cost-effective manner.[234]

The remarkable characteristic of this administrative model is its dependence on political intervention, chiefly through congressional action, to ensure that allocation decisions at the societal level and even the individual level are made fairly among the Medicare program and its beneficiaries. At the societal level, the independent ProPAC has no legal authority over setting hospital payment rates but serves chiefly to enhance Congress' ability to control the rate setting process politically. At the individual level, PRO's have more legal authority over hospitals and physicians in their care of Medicare beneficiaries. However, it has taken continual congressional oversight, legislation and prodding to get these organizations in a position to discharge their responsibilities as contemplated. Finally, the actual evidence of poor treatment of some patients under the prospective payment system emphasizes the need to have a strong and effective appeals process to protect the interests of individual beneficiaries in allocation decisions for Medicare resources.

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[232]Am. Hosp. Ass'n, Hospital Statistics, 1986 Edition, at xvii (1986).

[233]*See supra* note 151 and accompanying text.

[234]Technical Appendixes to the ProPAC Report and Recommendations to the Secretary, April 1, 1986, *supra* note 200, App. C, at 147.

Nevertheless, the Medicare prospective payment system has not really had to make truly hard choices about allocation of medical resources among its beneficiaries or providers. But the day may come, possibly when the federal budget deficit seriously and immediately threatens the national economy, when the federal government will be forced to make hard choices about the amount and allocation of medical resources in the Medicare program. Only such a challenge will reveal whether the administrative structure for the prospective payment system, designed expressly to assure quality and accessible health care services for Medicare beneficiaries, is equal to the task of making hard choices and resolving ethical dilemmas about the allocation of scarce medical resources at the societal and individual levels.

Bowen v. American Hospital Association: Federal Regulation Is Powerless to Save Baby Doe

Dennis F. Cantrell*

I. Introduction

On April 9, 1982, an infant boy, afflicted with Down's syndrome[1] and an esophageal obstruction which prevented oral feeding, was born in a Bloomington, Indiana hospital.[2] Although the esophageal obstruction was correctable with surgery,[3] the infant's parents refused to consent to any life-saving treatment.[4] On April 10, the hospital sought a court order to override the parents' decision, but a trial court denied the requested relief.[5] On April 12, the trial court permitted the local Child Protection Committee to review its decision, and after a hearing, the Committee did not disagree with the court's decision.[6] On April 14, the Indiana Court of Appeals denied a request for an immediate hearing.[7] Thereafter, the Indiana Supreme Court denied a petition for a writ of mandamus.[8]

Six days after his birth, the infant, known only as Baby Doe, died while a stay was being sought in the United States Supreme Court.[9] The treatment or, more precisely, the non-treatment of Baby Doe received national media coverage and sparked heated public debate.[10] Not only was an infant denied food, water, and surgical aid, but the decision to do so was also approved by a court of law.

Immediately following the death of Baby Doe, the federal government responded with its plan to protect other handicapped infants from passive euthanasia.[11] The Director of the Office of Civil Rights, Depart-

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[1]Bowen v. American Hosp. Ass'n, 106 S. Ct. 2101, 2107 (1986). Down's syndrome is a chromosomal abnormality which produces various degrees of mental retardation. *See infra* notes 25-28 and accompanying text.

[2]*Bowen*, 106 S. Ct. at 2107.

[3]Fost, *Putting Hospitals on Notice*, 1982 Hastings Center Report 5.

[4]*Id.*

[5]*Bowen*, 106 S. Ct. at 2107.

[6]*Id.*

[7]*Id.* at 2107-08, n.5.

[8]*Id.*

[9]*Id.* The Supreme Court later denied certiorari. Infant Doe v. Bloomington Hosp., 464 U.S. 961 (1983).

[10]Fost, *supra* note 3, at 5.

[11]Passive euthanasia is the term used when life-sustaining medical treatment is withdrawn

ment of Health and Human Services, following a directive from President Reagan, sent a letter on May 18, 1982, to 6,800 hospitals receiving federal aid, "reminding" them that denial of medical services to handicapped infants would violate section 504 of the Rehabilitation Act of 1973.[12] The letter warned that a violation of section 504 would result in the termination of federal financial assistance to participating hospitals.[13]

The Department of Health and Human Services (Department) thereafter promulgated an "Interim Final Rule" to enforce its position that section 504 prohibited the discriminatory failure to feed and care for handicapped infants.[14] The regulations required hospitals receiving federal financial assistance to post in a conspicuous place in delivery, maternity, and pediatric wards and nurseries, including intensive care nurseries, a notice stating that section 504 prohibits the discriminatory withholding of medical care from handicapped infants.[15] In addition, the notice was required to advise of the availability of a telephone "hotline" to report violations to the Department.[16] Finally, the Interim Final Rule also provided for expedited compliance actions and expedited access to hospital records and facilities whenever the Department determined that access was "necessary to protect the life or health of a handicapped individual."[17]

After the Interim Final Rule was invalidated by a federal district court,[18] the Department issued new "Proposed Rules," upon which it invited public comment.[19] The Proposed Rules mirrored the Interim Final Rules, except that the new rules required federally-assisted state child protective service agencies to implement their "full authority pursuant to State law to prevent instances of medical neglect of handicapped infants."[20] The Final Rules became effective on February 13, 1984.[21]

The United States Supreme Court, in *Bowen v. American Hospital*

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or withheld from a terminally ill patient by one other than the patient. *See* Perlman, Koulack & Tinney, *Developmental Defects*, in 1C R. GRAY, ATTORNEYS' TEXTBOOKS OF MEDICINE ¶ 17.53(5e) (3d ed. 1981).

[12]*Bowen*, 106 S. Ct. at 2108. Section 504 of the Rehabilitation Act of 1973 provides: "No otherwise qualified handicapped individual . . . shall, solely by reason for his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal Financial assistance . . . ." 29 U.S.C. § 794 (1985).

[13]*See infra* note 29.

[14]48 Fed. Reg. 9,630 (1983).

[15]*Id.* at 9,631.

[16]*Id.*

[17]*Id.* at 9,632.

[18]American Academy of Pediatrics v. Heckler, 561 F. Supp. 395 (D.D.C. 1983). *See infra* notes 40-41 and accompanying text.

[19]48 Fed. Reg. 30,846 (1983).

[20]*Id.* at 30,851.

[21]*Bowen*, 106 S. Ct. at 2109.

Association,[22] by a plurality vote, ruled that the regulations were not authorized by section 504 of the Rehabilitation Act of 1973.[23] The Final Rules represented an attempt by the executive branch of the federal government to regulate a highly complex and sensitive area of state law that was not previously subject to federal regulation.

This Article will briefly examine the nature and frequency of congenital infant birth defects and will examine the development and requirements of the Department's Final Rules. After analyzing the Supreme Court's decision in *Bowen*, the Article concludes that the Final Rules, although commendable in purpose, were properly invalidated because the Department has no authority to promulgate regulations interfering with the decisional process in the emergency medical treatment of newborn infants with severe birth defects.

II. The Nature and Frequency of Infant Birth Defects

The primary wish of expectant parents is that their infants are normal and healthy at birth. Unfortunately, there are thousands of severely deformed infants born in this country every year.[24] Despite modern medical technology, most of these infants can expect no more than a harshly limited and severely impaired life.

Infant birth defects vary in both the nature and degree of abnormality. The decision whether to withhold life-saving or life-sustaining medical treatment from impaired newborns is most often made in the case of a severe impairment. A severely impaired newborn is "one who is not likely to survive without surgical and medical intervention and whose prognosis, even assuming this intervention, may be poor in terms of cognitive life and minimal functioning."[25]

Baby Doe was born with one of the most common types of severe birth defects: Trisomy 21, or Down's syndrome, which is a chromosomal defect that causes varying degrees of mental retardation. At birth, it is impossible to predict accurately the potential degree of retardation, but the highest I.Q. that can be expected is 60.[26] Down's syndrome is usually accompanied by heart or bowel defects requiring immediate surgical treatment.[27] If such life-saving treatment is successfully performed, Down's

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[22]106 S. Ct. 2101 (1986).

[23]*Id.* at 2123.

[24]Two commentators have estimated that 30,000 infants are born in this country each year with severe birth defects. Brown & Truitt, *Euthanasia and the Right to Die*, 3 Ohio N.U.L. Rev. 615, 630-35 (1976).

[25]Ellis, *Letting Defective Babies Die: Who Decides?*, 7 Am. J. Law & Med. 394 (1982).

[26]*Id.* at 396.

[27]*Id.*

syndrome babies can expect a shorter than average life span of forty to sixty years.[28]

III. Federal Response to the Baby Doe Incident

The widely publicized story of Baby Doe did not fall on deaf ears in the nation's capital. The Department of Health and Human Services, following a directive from President Reagan, issued a letter on May 18, 1982, to 6,800 hospitals which receive federal financial assistance, such as Medicaid or Medicare.[29] The letter

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[28]*Id.* Other types of severe birth defects include anencephaly, a condition in which there is a partial or total absence of the brain; myelomeningocele (spina bifida cystica), a condition in which the baby's spinal cord is malformed and exposed; and encephalomeningocele, a condition in which an infant's brain protrudes from its skull. For an excellent, non-technical discussion of these and other severe birth defects, see *id.* at 395.

[29]The full text of the letter is as follows:

May 18, 1982

NOTICE TO HEALTH CARE PROVIDERS

SUBJECT: Discriminating Against the Handicapped by Withholding Treatment or Nourishment

There has recently been heightened public concern about the adequacy of medical treatment of newborn infants with birth defects. Reports suggest that operable defects have sometimes not been treated, and instead infants have been allowed to die, because of the existence of a concurrent handicap, such as Down's syndrome.

This notice is intended to remind affected parties of the applicability of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794). Section 504 provides that "No otherwise qualified handicapped individual . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . ." Implementing regulations issued by the Department of Health and Human Services make clear that this statutory prohibition applies in the provision of health services (45 C.F.R. 84.52) and that conditions such as Down's syndrome are handicaps within the meaning of section 504 (45 C.F.R. 84.3(j)).

Under Section 504 it is unlawful for a recipient of Federal financial assistance to withhold from a handicapped infant nutritional sustenance or medical or surgical treatment required to correct a life-threatening condition, if:

(1) The withholding is based on the fact that the infant is handicapped; and

(2) The handicap does not render the treatment or nutritional sustenance medically contraindicated.

For example, a recipient may not lawfully decline to treat an operable life-threatening condition in an infant, or refrain from feeding the infant, simply because the infant is believed to be mentally retarded.

We recognize that recipients of Federal financial assistance may not have full control over the treatment of handicapped patients when, for instance, parental consent has been refused. Nevertheless, a recipient may not aid or perpetuate discrimination by significantly assisting the discriminatory actions of another per-

reminded[30] hospitals of the federal government's position that section 504 of the Rehabilitation Act of 1973[31] prohibits the withholding of life-saving nutrition or medical treatment from handicapped infants.[32]

Although the letter recognized that a hospital does not have full control over the treatment of handicapped infants when parental consent to treatment has been refused, it warned hospitals to discharge the infant from the institution when the infant's parents refused consent to such treatment.[33] The letter also intimated that the discriminatory withdrawal of medical treatment or nourishment from handicapped infants would result in the termination of federal financial assistance to the hospital.[34]

The May 18, 1982, letter was not an idle threat. On March 7, 1983, the Department, contemplating a "vigorous federal role", promulgated an "Interim Final Rule," pursuant to section 504, to enforce its position with respect to the non-treatment of handicapped infants.[35] The Interim Rule required hospitals to post an informational notice "in a conspicuous place in each delivery ward, each maternity ward, each pediatric ward, and each nursery, including each intensive care nursery . . . ."[36] The notice

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son or organization. 45 C.F.R. 84.4(b)(1)(v). Recipients must accordingly insure that they do not violate section 504 by facilitating discriminatory conduct.

In fulfilling its responsibilities, a Federally assisted health care provider should review its conduct in the following areas to insure that it is not engaging in or facilitating discriminatory practices:

- Counseling of parents should not discriminate by encouraging parents to make decisions which, if made by the health care provider, would be discriminatory under section 504.
- Health care providers should not aid a decision by the infant's parents or guardian to withhold treatment or nourishment discriminatorily by allowing the infant to remain in the institution.
- Health care providers are responsible for the conduct of physicians with respect to cases administered through their facilities.

The failure of a recipient of Federal financial assistance to comply with the requirements of section 504 subjects that recipient to possible termination of Federal assistance. Moreover, section 504 does not limit the continued enforcement of State laws prohibiting the neglect of children, requiring medical treatment, or imposing similar responsibilities.

Betty Lou Dodson
Director, Office for Civil Rights.

47 Fed. Reg. 26,027 (1982).

[30]Although the letter purported to "remind" hospitals of the applicability of section 504 to medical treatment decisions, the letter was actually the first indication given by the government that it intended to enforce section 504 in that manner.

[31]29 U.S.C. § 794 (1985).

[32]*See supra* note 12.

[33]*See supra* note 29; *see also* 49 Fed. Reg. 1,631 (1984) (section 504 does not mandate hospital to overrule parental decision of non-treatment); *infra* note 96.

[34]*See supra* note 29.

[35]48 Fed. Reg. 9,630 (1983).

[36]*Id.* at 9,631.

was required to state that the "discriminatory failure to feed and care for handicapped infants in this facility is prohibited by federal law."[37] The notice was also to advise of the availability of a twenty-four hour telephone "hotline" to report violations to the Department.[38] Finally, the Interim Final Rule authorized expedited compliance actions and access to hospital records when "in the judgment of the responsible Department official," such access was "necessary to protect the life or health of a handicapped individual."[39]

In April of 1983, the United States District Court for the District of Columbia, in *American Academy of Pediatrics v. Heckler*,[40] struck down the Interim Final Rule as "arbitrary, capricious and promulgated in violation of the Administrative Procedure Act."[41] Undaunted by the court's decision, the Department issued a somewhat amended version of the Interim Final Rule as new "Proposed Rules" on July 5, 1983, and invited public comment.[42]

After the period for public comment had passed, the Department promulgated the Final Rules, which became effective February 13, 1984.[43] The new rules contained four mandatory provisions.[44] Like the Interim Final Rule, they required hospitals to post an informational notice which was to contain a statement either that section 504 prohibits discrimination on the basis of handicap,[45] or that "nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments."[46] In addition, the notice was to provide the telephone number of a 24-hour

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[37] *Id.*

[38] *Id.*

[39] *Id.* at 9,632.

[40] 561 F. Supp. 395 (D.D.C. 1983). The plaintiffs, American Academy of Pediatrics, National Associations of Children's Hospitals and Related Institutions and the Children's Hospital National Medical Center, brought suit to challenge the validity of the Interim Final Rule.

[41] *Id.* at 404. The District Court concluded that "haste and inexperience has resulted in agency action based on inadequate consideration" of a number of crucial factors. *Id.* at 399-401. Alternatively, the court ruled that the Department had improperly failed to solicit public comment in violation of the Administrative Procedure Act. *Id.*

[42] 48 Fed. Reg. 30,846 (1983).

[43] *Bowen*, 106 S. Ct. at 2109.

[44] The adopted code section already contained two other, non-mandatory subsections. Subsection (a) encouraged hospitals to establish Infant Care Review Committees (ICRC) to develop treatment standards for handicapped infants. 45 C.F.R. § 84.55(a) (1985). Subsection (f) provided that "[t]he activities of the ICRC will be guided by . . . the interpretive guidelines of the Department. . . ." 45 C.F.R. § 84.55(f)(1)(ii)(A) (1985). The Guidelines were only illustrative and set forth the Department's interpretation of Section 504.

[45] 45 C.F.R. § 84.55(b)(3) (1985).

[46] 45 C.F.R. § 84.55(b)(4) (1985).

"hotline" to the Department or the telephone number of the appropriate child protection agency.[47]

A second mandatory provision delineated the responsibilities of state child protective services agencies. This provision required these state agencies to adopt and enforce procedures utilizing their "full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants."[48] This provision also mandated (1) health care providers to report "known or suspected instances of unlawful medical neglect of handicapped infants;"[49] (2) a procedure so that state agencies receive timely reports;[50] (3) "on-site investigation" of hospitals, where appropriate;[51] (4) protection of infants by seeking legal action to obtain "timely court order[s] to compel the provision of necessary nourishment and medical treatment;"[52] and (5) timely notification to the Department of every complaint of "suspected unlawful medical neglect" of handicapped infants.[53]

The final mandatory sections authorized expedited access to records and expedited action to insure compliance.[54] Immediate access to patient records was authorized on a twenty-four hour basis, even in the absence of parental consent.[55] The Department was also clothed with authority to implement immediate action to effect compliance when "necessary to protect the life or health of a handicapped individual."[56] When a handicapped infant was in "imminent danger of death," the government was authorized to seek a temporary restraining order to sustain its life.[57]

The message conveyed in the Final Rules was clear and unequivocal. It was unlawful for hospitals receiving federal financial assistance to withhold or withdraw life-sustaining medical treatment from handicapped infants, regardless of whether parental consent was given or refused.

Not surprisingly, both sets of regulations met with immediate opposition. Several organizations filed lawsuits to enjoin enforcement of both the Interim Final Rule and the Final Rules.[58] These lawsuits progressed

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[47]45 C.F.R. § 84.55(b)(3)-(4) (1985).

[48]45 C.F.R. § 84.55(c)(1) (1985).

[49]45 C.F.R. § 84.55(c)(1)(i) (1985).

[50]45 C.F.R. § 84.55(c)(1)(ii) (1985).

[51]45 C.F.R. § 84.55(c)(1)(iii) (1985).

[52]45 C.F.R. § 84.55(c)(1)(iv) (1985).

[53]45 C.F.R. § 84.55(c)(1)(v) (1985). This subsection even applies "where a refusal to provide medically beneficial treatment is a result, not of decisions by a health care provider, but of decisions by parents." 49 Fed. Reg. 1,627 (1984).

[54]45 C.F.R. § 84.55(d)-(e) (1985).

[55]Access was authorized "when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual." 45 C.F.R. § 84.55(d) (1985).

[56]45 C.F.R. § 84.55(e) (1985).

[57]49 Fed. Reg. 1,628 (1984).

[58]*See infra* notes 59-64 and accompanying text.

through the federal courts and gave the Supreme Court the opportunity to rule on the validity of the regulations in *Bowen v. American Hospital Association*.

IV. *Bowen v. American Hospital Association*

A. Prior Litigation

On April 6, 1983, the American Hospital Association, along with two other organizations,[59] filed suit in federal court to restrain the enforcement of the Interim Final Rules.[60] In March, 1984, the parties amended their complaint and filed a motion to enjoin the enforcement of the Final Rules.[61] This action was consolidated with a separate, but related suit filed by the American Medical Association and other organizations.[62] The district court granted summary judgment in favor of the petitioners and enjoined enforcement of the Final Rules.[63] On appeal, the United States Court of Appeals for the Second Circuit summarily affirmed the ruling of the district court.[64]

The district court granted the requested relief solely on the authority of the Second Circuit decision in *United States v. University Hospital*,[65] which was also the authority upon which the Second Circuit summarily affirmed the judgment of the District Court.[66] Because *University Hospital* was found to be controlling, it is helpful to examine that case.

After the Department's Interim Final Rule was invalidated, but before the promulgation of the Final Rules, an infant, known as "Baby Jane Doe," was born with multiple congenital birth defects.[67] Baby Jane Doe was "transferred to University Hospital for dual surgery to correct her spina bifida and hydrocephalus."[68] Although the surgery was likely to prolong the infant's life, it would not have improved her handicapped conditions, including probable mental retardation.[69] After consulting with several physicians and other advisers, her parents decided to forgo the

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[59]Also party plaintiffs were the Hospital Association of New York State and Strong Memorial Hospital of the University of Rochester.

[60]American Hosp. Ass'n v. Heckler, 585 F. Supp. 541 (S.D.N.Y. 1984); *see also* Ahern, *Baby Doe: AHA Prevails in Supreme Court*, Health Law Vigil, June 20, 1986, at 1.

[61]Ahern, *supra* note 60.

[62]*Id.*

[63]American Hosp. Ass'n v. Heckler, 585 F. Supp. 541, 542 (S.D.N.Y. 1984).

[64]*Bowen*, 106 S. Ct. at 2109.

[65]729 F.2d 144 (2d Cir. 1984).

[66]*Bowen*, 106 S. Ct. at 2109.

[67]*Id.* She suffered from myelomeningocele (spina bifida), microencephaly (an abnormally small head), and hydroencephalus (fluid in the cranial vault). United States v. University Hosp., 729 F.2d 144, 146 (2d Cir. 1984).

[68]*University Hosp.*, 729 F.2d at 146.

[69]*Id.*

corrective surgery, and instead opted for "conservative" medical treatment.[70]

Five days after Baby Jane Doe's birth, an unrelated Vermont attorney filed suit in the New York State Supreme Court requesting the appointment of a *guardian ad litem* and an order directing the hospital to perform the surgery for the infant.[71] The trial court granted the requested relief, but was promptly reversed by the New York Appellate Division on the ground that the " 'concededly concerned and loving parents' "[72] chose a course of appropriate medical treatment which was "in the best interest of the infant."[73] The New York Court of Appeals affirmed the decision of the Appellate Division on the different ground that the trial court had no jurisdiction to entertain a child neglect proceeding by a stranger who had not requested aid from the appropriate state agency.[74]

During the course of the state proceedings, the Department received an anonymous complaint "that Baby Jane Doe was being discriminatorily denied medical treatment on the basis of her handicaps."[75] The Department referred the complaint to the New York State Child Protective Service, which investigated and concluded that there was no basis for state intervention.[76] Before the state agency reached its conclusion, however, the Department made several requests to the hospital for inspection of the medical records to enable it to decide whether section 504 had been violated.[77] The hospital refused to comply on the grounds that Baby Jane Doe's parents had not consented to a release of her medical records and that the Department's jurisdiction was doubtful.[78]

The Department thereafter filed suit in federal court pursuant to a regulation that authorized Departmental access to information necessary to ascertain compliance with section 504.[79] After the parents were allow-

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[70] *Id.* The treatment consisted of "good nutrition, the administration of antibiotics, and the dressing of the baby's exposed spinal sac." *Id.*

[71] *Id.*

[72] *Id.* at 147 (quoting the Appellate Division of the New York Supreme Court).

[73] *Id.*

[74] *Id.* (quoting the New York Court of Appeals).

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.* at 148.

[79] *Id.* The pertinent regulation provided:

> (c) *Access to sources of information.* Each recipient [of Federal financial assistance] shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this part. . . . Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part.

45 C.F.R. § 80.6(c) (1985), *as incorporated by* 45 C.F.R. § 84.61 (1985).

ed to intervene, the district court ruled that the government had no right of access to the records because the hospital had not violated section 504.[80] According to the court, the hospital " 'failed to perform the surgical procedures in question, not because Baby Jane Doe [was] handicapped, but because her parents ha[d] refused to consent . . . .' "[81]

The court of appeals agreed with the district court that the attempt by the Department to gain access to Baby Jane Doe's medical records was beyond the authority granted to it by Congress.[82] The court of appeals went further than the district court, however, by ruling that section 504 was never meant to apply to treatment decisions involving impaired newborns.[83] In the court's view, Baby Jane Doe was not "otherwise qualified" within the meaning of section 504 because "where medical treatment is at issue, it is typically the handicap itself that gives rise to, or at least contributes to the need for services."[84] Because "the handicapping conditions is related to the condition(s) to be treated, it will rarely, if ever, be possible to say with certainty that a particular decision was 'discriminatory'."[85] The court of appeals concluded that until Congress indicates otherwise, "it would be an unwarranted exercise of judicial power to approve the type of investigation that ha[d] precipitated this lawsuit."[86]

The Department did not seek certiorari in *University Hospital*. The Supreme Court granted certiorari in *Bowen v. American Hospital Association*.[87]

B. The Supreme Court Decision in Bowen

The plurality[88] opinion began by narrowly circumscribing the scope of review. According to the plurality, the only issue before the Court was whether the four mandatory provisions of the Final Rules were authorized by section 504.[89] The plurality expressly refused to decide

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[80]*University Hosp.*, 729 F.2d at 148-49.

[81]*Id.* at 148 (quoting United States v. University Hosp., 575 F. Supp. 607, 614 (S.D.N.Y. 1983)).

[82]*Id.* at 161.

[83]*Id.*

[84]*Id.* at 156. The court stated that "the phrase 'otherwise qualified' is geared toward relatively static programs or activities such as education, . . . employment, . . . and transportation systems. . . . As a result, the phrase cannot be applied in the comparatively fluid context of medical treatment decisions without distorting its plain meaning." *Id.* (citations omitted). The court noted that the phrase " 'refers to a person who is qualified *in spite of* her handicap . . . .' " *Id.* (quoting Doe v. New York Univ., 666 F.2d 761 (2d Cir. 1981)).

[85]*Id.* at 157. The court noted that the hospital was always willing to perform the surgery if Baby Jane Doe's parents consented. *Id.* at 160.

[86]*Id.* at 161.

[87]105 S. Ct. 3475 (1985).

[88]The opinion was authored by Justice Stevens, in which Justices Marshall, Blackmun and Powell joined. Chief Justice Burger concurred in the judgment. Justices White, Brennan and O'Connor dissented. Justice Rehnquist took no part in the consideration or decision of the case.

[89]*Bowen*, 106 S. Ct. at 2111. The District Court's ruling, summarily affirmed by the

whether section 504 "ever applies to individual medical treatment decisions involving handicapped infants."[90]

The validity of the mandatory components of the Final Rules depended upon whether the Department's explanation of the need for the rules "included a 'rational connection between the facts found and the choice made.' "[91] Although the plurality recognized that the Department was entitled to some deference with respect to its reasoning, the plurality cautioned that an agency regulation will not be upheld merely because "it is possible to 'conceive a basis' for administrative action."[92]

The plurality applied this standard to the two justifications offered by the Department for the promulgation of the Final Rules.[93] The Depart-

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Second Circuit, declared " '[t]he Final Regulation . . . invalid and unlawful as exceeding' " Section 504, enjoined the Department from "any further implementation of the Final Regulation," and declared invalid and enjoined "[a]ny other actions" of the Department "to regulate treatment involving impaired newborn infants taken under authority of Section 504, including currently pending investigation and other enforcement actions." *Id.* at 2111, n.11 (quoting American Hosp. Ass'n v. Heckler, 585 F. Supp. 541, 542 (S.D.N.Y. 1984)).

[90]*Id.* at 2111. In footnote 11, the plurality narrowly construed the language of the injunction by noting that the complaints filed by the plaintiffs challenged only the validity of the Final Rules, not the Department's authority to regulate all treatment decisions. The plurality also was of the opinion that the Court of Appeals intended only to enjoin the current regulations, not all possible activity that might involve the medical treatment of handicapped infants. The dissent took exception with this narrow construction. *See infra* notes 120-125 and accompanying text.

[91]*Bowen*, 106 S. Ct. at 2112 (quoting Motor Vehicles Mfrs. Ass'n v. State Farm Mut., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962))).

[92]*Id.*

[93]Before examining the Department's two justifications, the plurality reviewed the pre-existing state law mechanisms that governed the provision of medical care to handicapped infants:

> In broad outline, state law vests decisional responsibility in the parents, in the first instance, subject to review in exceptional cases by the State acting as *parens patriae.* Prior to the regulatory activity culminating in the Final Rules, the federal government was not a participant in the process of making treatment decisions for newborn infants. We presume that this general framework was familiar to Congress when it enacted § 504.

Id. at 2113 (footnote omitted). The plurality also cited a 1983 government report:

> "The paucity of directly relevant cases makes characterization of the law in this area somewhat problematic, but certain points stand out. First, there is a presumption, strong but rebuttable, that parents are the appropriate decision-makers for their infants. Traditional law concerning the family, buttressed by the emerging constitutional right of privacy, protects a substantial range of discretion for parents. Second, as persons unable to protect themselves, infants fall under the *parens patriae* power of the state. In the exercise of this authority, the state not only punishes parents whose conduct has amounted to abuse or neglect of their children but may also supervene parental decisions before they become operative to ensure that the choices made are not so detrimental to a child's interests as to amount to neglect and abuse.
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> ". . . [A]s long as parents choose from professionally accepted treatment options the choice is rarely reviewed in court and even less frequently supervened.

ment's first argument was that a hospital discriminates within the meaning of section 504 by failing to furnish a handicapped infant with medically beneficial treatment "solely by reason of his handicap."[94] Second, the Department contended that a hospital may violate section 504 by failing to report incidents of medical neglect to a state child protective agency.[95] Both justifications were rejected by the plurality.

The plurality first ruled that as a matter of law, a hospital cannot violate section 504 by withholding medical treatment from a handicapped newborn when the infant's parents have refused consent to the treatment.[96] Without parental consent, a hospital does not have the right to provide treatment to an infant.[97] Under such circumstances, an "infant is neither 'otherwise qualified' for treatment nor has he been denied care 'solely by reason of his handicap.' "[98]

From this conclusion, the plurality reasoned that the Final Rules are not necessary to prevent hospitals from denying medical care to handicapped newborns.[99] If parental consent to treatment is withheld, a hospital has no legal right to provide medical treatment to a handicapped infant. Therefore, a hospital could violate section 504 only by refusing to treat a handicapped infant when parental consent to such treatment has been given. According to the plurality, however, the Department offered no evidence of any instance where a hospital refused medical treatment when parental consent had been obtained.[100] The Department also did not at-

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> The courts have exercised their authority to appoint a guardian for a child when the parents are not capable of participating in the decisionmaking or when they have made decisions that evidence substantial lack of concern for the child's interests. Although societal involvement usually occurs under the auspices of governmental instrumentalities—such as child welfare agencies and courts—the American legal system ordinarily relies upon the private initiative of individuals, rather than continuing governmental supervision, to bring the matter to the attention of legal authorities."

Id. at 2113, n.13 (quoting REPORT OF THE PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH 212-214 (1983) (footnotes omitted)).

[94]*Id.* at 2113.

[95]*Id.*

[96]*Id.* at 2114. Although the Department originally thought that a hospital's duty to provide treatment was unaffected by the absence of parental consent, even the Department conceded, in the preamble to the Final Rules that when "a non-treatment decision, no matter how discriminatory, is made by parents, rather than by the hospital, section 504 does not mandate that the hospital unilaterally overrule the parental decision and provide treatment notwithstanding the lack of consent." 49 Fed. Reg. 1,631 (1984).

[97]*Bowen*, 106 S. Ct. at 2114. According to the plurality, "[i]ndeed, it would almost certainly be a tort as a matter of state law to operate on an infant without parental consent." *Id.*

[98]*Id.*

[99]*Id.* at 2115.

[100]*Id.*

tempt to argue that posted notices, "hotlines," or on-site investigations were needed to prevent hospitals from denying treatment to which parents had consented.[101]

Thus, according to the plurality, the supposed need for federal regulations was not demonstrated by any evidence. In every case that the Department cited to support its argument that hospitals were discriminatorily denying medical treatment, the hospital's refusal was based upon the absence of parental consent.[102] Moreover, in the three cases cited by the Department as "providing the strongest support for federal intervention," not only was parental consent refused, but the effectiveness of existing state mechanisms was demonstrated because surgery was ordered by state authorities after the hospitals sought judicial intervention.[103]

The plurality also considered an argument not advanced by the Department, but which, according to the dissent, was pivotal to the validity of the Final Rules.[104] The dissent maintained that the Final Rules were justified to curtail discriminatory advice by physicians who recommended withholding medical treatment for handicapped newborns because of their handicaps.[105] The plurality, noting that the Department had not even advanced this theory,[106] rejected the dissent's reasoning on a number of grounds. First, the regulations in no way constrained the type of advice physicians may give to their patients.[107] Second, because section 504 does not prohibit parents from refusing consent to medical treatment for handicapped newborns, section 504 may not "prevent the giving of advice to do something which [the statute] does not itself prohibit."[108] Finally, even if attitudinal surveys showed that physicians would acquiesce in, or fail

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[101] *Id.*

[102] The plurality maintained:

> The Secretary's belated recognition of the effect of parental nonconsent is important, because the supposed need for federal monitoring of hospitals' treatment decisions rests *entirely* on instances in which parents have refused their consent. Thus, in the Bloomington, Indiana, case that precipitated the Secretary's enforcement efforts in this area, as well as in the *University Hospital* case that provided the basis for the summary affirmance in the case now before us, the hospital's failure to perform the treatment at issue rested on the lack of parental consent. The Secretary's own summaries of these cases establish beyond doubt that the respective hospitals did not withhold medical care on the basis of handicap and therefore did not violate § 504; as a result, they provide no support for his claim that federal regulation is needed in order to forestall comparable cases in the future.

Id. at 2115 (footnotes omitted).

[103] *Id.* at 2116-17.

[104] *Id.* at 2117, n.22.

[105] *Id.* at 2129 (White, J., dissenting).

[106] *Id.* at 2117, n.22.

[107] *Id.*

[108] *Id.*

to correct, "bad" decisions by parents, there was no evidence that "the parental decisionmaking process is one in which doctors exercise the decisive influence needed to force such results."[109] The plurality thus found no justification for the Final Rules based upon the premise that physicians may violate section 504 by urging parents to decide against treating handicapped newborns.

The plurality also rejected the second justification the Department offered for the Final Rules. The Department maintained that hospitals violated section 504 by failing to report parental decisions to withhold treatment to the appropriate state agencies, and that past failures to report justified federal regulation.[110] The plurality first ruled that section 504 itself imposes no duty upon hospitals to report instances of discriminatory medical treatment.[111] Second, although a hospital could violate section 504 by selectively refusing to report medical neglect, the Department had again proffered no evidence that such conduct had occurred.[112] Third, and perhaps most importantly, the Final Rules did not directly require hospitals to report instances of medical neglect; rather, the Final Rules required state agencies to use their "full authority" to "prevent instances of unlawful medical neglect of handicapped infants."[113]

After finding that the purpose of section 504 was not to impose "an affirmative-action obligation" on recipients of federal financial aid,[114] the plurality found that section 504 did not authorize an affirmative-action command to state agencies with respect to the way they conducted medical neglect investigations.[115] The Court expressly rejected the notion that the

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[109]*Id.* at 2118, n.22.

[110]*Id.* at 2118.

[111]*Id.*

[112]*Id.*

[113]*Id.* at 2119 (citing 45 C.F.R. § 84.55(c)(1) (1985) (footnote omitted). The plurality contended that the Final Rules effectively made handicapped newborns a state investigative priority, with the result that state agencies would necessarily shift scarce resources away from other enforcement activities. Moreover, the Final Rules directly contradicted established state law with respect to mechanisms to investigate the medical neglect of handicapped infants, such as the state law requirement of confidentiality of records. *Id.*

[114]*Id.* According to the plurality, section 504 only "seeks to assure even-handed treatment," and has never been authority to impose an affirmative-action obligation on recipients of federal financial aid. *Id.* (quoting Southeastern Community College v. Davis, 442 U.S. 397, 411 (1979)).

[115]*Id.* at 2120. The plurality concluded:

> State child protective services agencies are not field offices of the HHS bureaucracy, and they may not be conscripted against their will as the foot soldiers in a federal crusade. As we stated in *Alexander v. Choate*, 469 U.S., at ____, 105 S. Ct., at 724, "nothing in the pre- or post-1973 legislative discussion of § 504 suggests that Congress desired to make major inroads on the States' long-standing discretion to choose the proper mix" of services provided by state agencies.

Id. (footnote omitted).

Department, pursuant to section 504, may force state agencies to enforce compliance with section 504 by other recipients of federal funds, such as hospitals.

The plurality, then, ruled that the four mandatory components of the Final Rules were invalid because they were not authorized by section 504.[116] Not only did the plurality rule that there was not an adequate evidentiary foundation for the Final Rules, but it also was concerned by what it perceived to be an unauthorized and unwarranted intrusion of federal power into an otherwise exclusive domain of state authority.[117] Without evidence to the contrary, the plurality was unwilling to authorize "federal intervention into a historically state-administered decisional process that appears . . . to be functioning in full compliance with [section] 504."[118] In short, the plurality ruled that "[s]ection 504 does not authorize the Secretary to give unsolicited advice either to parents, to hospitals, or to state officials who are faced with difficult treatment decisions concerning handicapped children."[119]

The dissent, authored by Justice White, disagreed with the plurality's narrow construction of the proper scope of the Court's review of the lower court decision.[120] According to the dissent, the issue was not whether the Final Rules were invalid, but whether section 504 may ever authorize the Department to regulate medical treatment decisions involving handicapped newborns."[121] This broader scope of review was necessary because

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[116]*Id.* at 2123.

[117]In footnote 33, the plurality reasoned:

> The legislative history of the Rehabilitation Act does not support the notion that Congress intended intervention by federal officials into treatment decisions traditionally left by state law to concerned parents and the attending physicians, or, in exceptional cases, to state agencies charged with protecting the welfare of the infant. As the Court of Appeals noted, there is nothing in the legislative history that even remotely suggests that Congress contemplated the possibility that "section 504 could or would be applied to treatment decisions, involving defective newborn infants." 729 F.2d 144, 159 (1984).
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> "As far as can be determined, no congressional committee or member of the House or Senate ever even suggested that section 504 would be used to monitor medical treatment of defective newborn infants or establish standards for preserving a particular quality of life. No medical group appeared alert to the intrusion into medical practice which some doctors apprehend from such an undertaking, nor were representatives of parents or spokesmen for religious beliefs that would be affected heard." *Id.* at 158 (quoting American Academy of Pediatrics v. Heckler, 561 F. Supp. at 401).

Id. at 2122, n.33.

[118]*Id.* at 2122.

[119]*Id.* at 2123.

[120]Justice White's dissent was in five parts. Justice Brennan joined in the dissent, while Justice O'Connor joined in parts I, II, IV, and V of the dissent.

[121]*Bowen*, 106 S. Ct. at 2123 (White, J., dissenting).

the district court's judgment, summarily affirmed by the Court of Appeals, permanently enjoined the Secretary from " 'continuing or undertaking any other actions to investigate or regulate treatment decisions involving impaired newborn infants taken under authority of section 504, including pending investigations and other enforcement actions.' "[122] Thus, in the dissent's opinion, the Department was completely prohibited from regulating the medical treatment of handicapped newborns via section 504.[123] This conclusion was further compelled by *University Hospital*,[124] the decision which directly controlled the lower courts' decision in this action, in which the court of appeals ruled that section 504 could never apply to medical treatment decisions because handicapped infants are not "otherwise qualified" within the meaning of section 504.[125]

The dissent concluded that there are situations in which section 504 may apply to medical treatment decisions for newborns.[126] The example given by the dissent is where a Down's syndrome infant suffers from an esophageal obstruction. The infant would be "otherwise qualified" for surgery to correct the obstruction because this condition is assumed to be unrelated to the Down's syndrome.[127] Thus, "[i]f an otherwise normal child would be given the identical treatment, so should the handicapped child if discrimination on the basis of handicap is to be avoided."[128] Because there are situations in which handicapped infants are "otherwise qualified" for treatment, section 504 would apply to such medical treatment decisions; the dissent would, therefore, have reversed the court of appeals' judgment.[129]

The dissent, though, went much further than simply arguing that the Department is not absolutely precluded from regulating medical treatment decisions pursuant to section 504. The dissent also maintained that section 504 authorized the mandatory components of the Final Rules.[130] The dissent found an adequate evidentiary basis for the Final Rules because the evidence indicated that discrimination may occur in situations other than where a hospital refuses to treat a handicapped infant when parental consent has been given.[131] Doctors and hospitals substantially influence parental decision-making with respect to the treatment of handicapped

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[122] *Id.* at 2124 (citation omitted).

[123] *Id.*

[124] 729 F.2d 144 (2d Cir. 1984).

[125] *Bowen*, 106 S. Ct. at 2125 (White, J., dissenting).

[126] *Id.* at 2127.

[127] *Id.*

[128] *Id.* (footnote omitted).

[129] *Id.* at 2128.

[130] *Id.* at 2130. The dissent, though, stated it addressed this issue only because the plurality did. *Id.* at 2128.

[131] *Id.* at 2129-30.

newborns. If doctors make discriminatory treatment recommendations to parents, the doctors would violate section 504 whether or not the parents followed their recommendations.[132]

The dissent was convinced that the Department intended to prevent this "elusive" form of discrimination through the Final Rules.[133] The lack of evidence to support the conclusion that such discriminatory practices existed did not invalidate the Final Rules because the dissent agreed with the Department that the Final Rules could properly be prophylactic in nature.[134] Thus, the dissent found a rational connection between the facts found and the regulatory choice made and would not have invalidated the regulations.[135]

V. The Final Rules Were Correctly Invalidated

The only unambiguous result of *Bowen v. American Hospital Association* is that the Final Rules at issue were invalidated. At least three Justices were of the opinion that the Department has authority, pursuant to section 504, to regulate medical treatment decisions involving handicapped newborns.

For this reason, and because the plurality expressly narrowed its opinion to the validity of the Final Rules, the Department will presumably continue to attempt to regulate the area of medical treatment for severely impaired infants. It is difficult, however, to conceptualize any set of regulations that would, or even should, be authorized by section 504 absent express congressional directives.[136]

The Final Rules issued by the Department represented the administration's response to a situation it found deplorable: handicapped infants are allowed to die when the means exist to prolong their lives. The clear purpose of the Final Rules was to prevent, when possible, the practice of passive euthanasia on handicapped infants. To accomplish this goal, the Department chose to utilize section 504.

The fundamental flaw in the Department's attempt to utilize section 504 for this purpose is that it ignored the true cause of the problem: lack of parental consent. Current state common law principles vest parents with the responsibility to make treatment decisions for their children, subject to review by the state acting as *parens patriae* in exceptional cases.[137] The Final Rules did not, nor can any future rules under section 504, prevent parents from exercising their authority to refuse consent to medical

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[132] *Id.* at 2129.

[133] *Id.*

[134] *Id.* at 2130.

[135] *Id.*

[136] *See supra* note 86 and accompanying text.

[137] *See supra* note 117.

treatment for their severely impaired newborns. If parental consent to life-saving medical treatment is refused, and if there is no judicial intervention, a hospital has no authority to perform the medical procedures. Moreover, whenever parental consent is withheld, section 504 can not be used to force hospitals to provide the medical treatment.

The Final Rules, then, were designed to undermine indirectly parental authority to withhold consent to medical treatment, but the rules were necessarily directed to hospitals and state child protective services agencies. The fundamental premise of the Final Rules was that it is unlawful, under section 504, for a hospital to withhold or counsel against medical treatment for handicapped infants, solely because of their handicaps. By requiring posted notices, "hotlines," federal investigative "armies," access to confidential records, and expedited compliance actions, the Final Rules, under the guise of preventing discrimination, were really designed to cause hospitals to fear the loss of federal financial assistance if they, in any manner, counseled parents to withhold medical treatment from handicapped newborns.

The plurality in *Bowen* correctly determined that section 504 did not countenance such federal intrusion. Even if an indirect attempt to undermine parental authority had been a legitimate goal, the very existence of parental authority was fatal to the validity of the Final Rules. If parental consent to treatment is not given, a hospital cannot violate section 504 by withholding treatment. If parental consent to treatment is given, a hospital can violate section 504 by withholding treatment, but it cannot be seriously contended that a hospital would ever withhold such treatment against the wishes of parents.[138]

The justification, then, for the Final Rules can only depend upon alleged discriminatory conduct by doctors or hospitals *before* consent to treatment is given or refused.[139] The dissent in *Bowen* vigorously argued that doctors or hospitals can discriminate within the meaning of section 504 by advising parents to withhold medical treatment from handicapped infants merely because they are handicapped. The dissent agreed, however, that parents have the right to refuse medical treatment solely by reason for the infant's handicapped conditions.[140] The conclusion, then, is that the Department utilized section 504 in an attempt to prohibit doctors or

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[138]The Department proffered no such evidence and, moreover, as the plurality in *Bowen* noted, the parental interest in calling attention to a refusal by a hospital to perform treatment adequately vindicates the interest in enforcing section 504 for that reason. *Bowen*, 106 S. Ct. at 2115. *See supra* note 100 and accompanying text.

[139]The failure of a hospital to report discriminatory treatment can violate section 504, but, again, the Department offered no such evidence and the cases proved otherwise. *See supra* note 112 and accompanying text.

[140]*Bowen*, 106 S. Ct. at 2128, n.10.

hospitals from disclosing to parents that withholding medical treatment from severely impaired newborns is a legitimate medico-legal decision.

Apart from whether the Final Rules were authorized by section 504, the rules represented an ineffective and counter-productive effort to accomplish the true goal—prohibiting the passive euthanasia of severely handicapped infants. If that goal is ever to be accomplished, the true issue that must be resolved is whether parents should continue to have the authority to decide to withhold life-saving or life-sustaining medical treatment from a severely impaired infant based upon a subjective assessment of the potential quality of the infant's expected life.

Our society has, thus far, made a value judgment that parents are the most appropriate decision-makers for their infants, subject to judicial intervention in exceptional cases. As long as this fundamental premise remains viable, a continual effort should be made to ensure that the decision-making process is conducted in the best possible manner with respect to the interests of the infant, its parents, and society. This decision-making process involves complex clinical facts, moral considerations, and difficult, imprecise judgments. Hospitals continually seek to establish meaningful policies and procedures to improve the quality of the decision-making process.[141]

Even if there were an evidentiary foundation for the proposition that doctors or hospitals discriminate in counseling parents of handicapped infants, and even if the purpose of the Final Rules was to improve the quality of care for handicapped infants, the Department's attempts to enforce the rules effectively demonstrated that the rules were counter-productive and actually reduced the quality of care of newborns. The American Hospital Association (AHA), in a letter to the Department on September 2, 1983,[142] in which the AHA commented on the Proposed Rules, described the effects of the federal enforcement mechanisms in several hospitals and concluded,

> The unfortunate consequences of these actions were the disruption of operating procedures designed for the protection of newborns, postponement or interruption of necessary medical treatment of severely-ill infants, and, in at least one case, substantial risk to the health of a child. In sum, these procedures ostensibly designed to enhance the medical care of infants actually

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[141]Many hospitals are implementing institutionally based Bioethical Review Committees. Such committees are made up of clergy, social workers, physicians, nurses and administrators to help parents in the decision-making process.

[142]Letter from American Hospital Association to Director, Office of Civil Rights, Department of Health & Human Services (September 2, 1983) (discussing Proposed Rules stated at 48 Fed. Reg. 30,846 (1983)).

reduced the quality of care that otherwise would have been given pursuant to hospital and medical practice.[143]

Until our society decides to prohibit the withholding of life-saving or life-sustaining medical treatment from handicapped newborns, current efforts to improve the quality of the decision-making process should continue. Federal intervention through the use of section 504, which was never meant to apply to medical treatment decisions,[144] will only impair the operation of existing state mechanisms designed to oversee that process. Whether correct or morally outrageous, the law as it presently exists allows such decisions to be made. Section 504, under the guise of preventing discrimination, is not the proper vehicle for attempting to change existing state procedures.

VI. Conclusion

The plurality in *Bowen v. American Hospital Association* correctly concluded that the Final Rules were not authorized by section 504 of the Rehabilitation Act of 1973. The door remains open, though, for the Department of Health and Human Services to draft new rules to regulate medical treatment of handicapped infants. However, unless the Department can fill an obvious evidentiary void, it is not likely that any new regulations would survive judicial scrutiny. The presence or absence of parental consent will remain the pivotal factor affecting the validity of any new regulations or enforcement proceedings.

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[143] *Id.* at 4.

[144] *See supra* notes 115-18 and accompanying text.

Note

Denying Hospital Privileges to Non-Physicians: Does Quality of Care Justify a Potential Restraint of Trade?

I. Introduction

Much of the recent increase in antitrust litigation in the health care field is due to suits by health care professionals alleging antitrust violations when hospitals have denied them staff privileges.[1] In addition to individual physicians, non-physician health care providers such as podiatrists, clinical psychologists, nurse-midwives, nurse-anesthetists, and chiropractors seek hospital privileges and have legally challenged privilege denials.[2] The large number of cases indicates the strength of the competing interests involved.[3] For a health professional, access to a hospital is vital to fully practice his profession. For a hospital, the ability to be selective in choosing its staff is vital to the quality of its service.

A plaintiff's allegation that the denial of privileges is an illegal group boycott and the hospital's assertion in defense that it must maintain its quality of care present special problems to an antitrust court. The variety and inconsistency of judicial approaches to analyzing quality of care as a justification for exclusion[4] suggest the difficulty of reconciling these competing interests under the antitrust laws in a way that prevents anticompetitive abuses without interfering with the legitimate functioning of hospitals. In struggling with these cases, courts have not adequately distinguished between denial of privileges to an individual physician and exclusion of an entire group of non-physicians.[5] However, there are clear

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[1]Nearly half of health care antitrust cases involve staff privileges. *Attempts to Gain Access to Hospitals Are Prevalent in Health Care Actions*, [Jan.-June] Antitrust & Trade Reg. Rep. (BNA) No. 1150, at 187 (Feb. 2, 1984).

[2]*See, e.g.*, Bhan v. NME Hosp., Inc., 772 F.2d 1467 (9th Cir. 1985) (nurse-anesthetist); Wilk v. American Medical Ass'n, 719 F.2d 207 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984) (chiropractors); Kaczanowski v. Medical Center Hosp. of Vt., 612 F. Supp. 688 (D. Vt. 1985) (podiatrists); Nurse Midwifery Assocs. V. Hibbett, 54 F. Supp. 1185 (M.D. Tenn. 1982) (nurse-midwives); *Ohio Charges Accreditation Association with Preventing Competition in Provision of Psychological Care*, [Jan.-June] Antitrust & Trade Reg. Rep. (BNA) No. 948, at D-2 (Jan. 24, 1980) [hereinafter *Ohio Charges Accreditation Association*] (clinical psychologists).

[3]Enders, *Antitrust and Health Care: Reconciling Competing Values—Medical Staff Issues*, 6 Whittier L. Rev. 737, 737 (1984).

[4]*See infra* notes 118-38 and accompanying text.

[5]*See infra* notes 118-44 and accompanying text.

differences between quality of care as a rationale for excluding an individual physician and as a justification for barring a group of non-physicians. Because of these differences, exclusion of a group merits heightened antitrust scrutiny.

Beginning with an overview of group boycott law, this Note discusses the issue of hospital privileges, focusing on specific non-physician groups seeking privileges. After examining a denial of privileges as a group boycott and quality of care as a defense, this Note surveys judicial approaches to such a defense. As this Note will show, there are significant differences between a quality of care rationale asserted against individuals and asserted against groups. Because of these differences, primarily the greater potential anticompetitive effects of excluding an entire group of competitors, this Note concludes with a recommendation that judicial scrutiny of quality of care as a defense be based on a substantial relation and least restrictive alternative test when quality is asserted as a justification for excluding a group. A court should demand that a quality standard invoked to deny privileges to non-physicians be substantially related to the procompetitive justification asserted for the standard and that the standard be the least restrictive alternative for achieving that procompetitive justification.

II. Overview of Antitrust Law

Section one of the Sherman Act states that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."[6] Relatively early in the history of litigation under this provision, the United States Supreme Court decided that Congress could not have intended such a potentially broad proscription of trade.[7] The Court, therefore, formulated the "rule of reason," declaring that only conduct that unreasonably restrains trade violates the Sherman Act.[8] Under the rule of reason, a court analyzes in detail the challenged conduct in a specific market and weighs the procompetitive and anticompetitive effects. Where anticompetitive effects predominate, the conduct will be declared unreasonably restrictive of trade, thus illegal.[9]

Because applying the rule of reason consumed much judicial time and because certain practices were repeatedly found to be anticompetitive in various contexts, the Court has, over the years, declared certain trade

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[6]15 U.S.C. § 1 (1982).

[7]Standard Oil Co. v. United States, 221 U.S. 1, 60 (1911). Because a contract to sell a product to one buyer effectively precludes others from buying that particular product, a literal reading of section one could conceivably bar all contracts to sell. *Id.*

[8]*Id.*

[9]National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 690-92 (1978).

restrictions per se illegal.[10] Having specific, clearly defined per se offenses conserves judicial time and enhances predictability in the conduct of business.[11] Because a per se offense includes a presumption of anticompetitive effect,[12] a plaintiff need not show the challenged conduct has an anticompetitive effect in a specific market, but only that a defendant did the act alleged.

One type of conduct that has been accorded per se status is a group boycott or concerted refusal to deal,[13] recently defined by the Court as "joint efforts . . . to disadvantage competitors by 'either directly denying or persuading or coercing suppliers or customers to deny relationships the competitors need in the competitive struggle.' "[14] A group boycott is a somewhat amorphous offense because almost any joint conduct that results in denial of a business relationship to a competitor may be characterized as a group boycott.[15] Therefore, the courts have not found that anything a plaintiff labels a group boycott is per se illegal, but have instead applied the rule of reason in certain contexts, so that only conduct with clearly anticompetitive effects would be found illegal.[16] Group boycotts thus became a quasi per se offense. In *Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co.*,[17] the Supreme Court attempted to clarify the confusion in group boycott law by declaring that only where a plaintiff can show that a defendant "possesses market power or exclusive access to an element essential to effective competition,"[18] may a court find an alleged group boycott per se illegal.[19] Where a plaintiff cannot make this showing, the alleged group boycott should be evaluated under the rule of reason.[20]

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[10]Northern Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (listing price fixing, division of markets, group boycotts, and tying arrangements as per se offenses).

[11]Arizona v. Maricopa County Medical Soc'y, 457 U.S. 332, 343-44 (1982).

[12]*Id.*

[13]Silver v. New York Stock Exch., 373 U.S. 341, 347-48 (1963); Klor's v. Broadway-Hale Stores, 359 U.S. 207, 212 (1959).

[14]Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co., 105 S. Ct. 2613, 2619 (1985) (quoting L. SULLIVAN, LAW OF ANTITRUST 261-62 (1977)).

[15]P. AREEDA, ANTITRUST ANALYSIS ¶ 370 (3d ed. 1981) ("boycotts are not a unitary phenomenon").

[16]*See, e.g.*, Kreuzer v. American Academy of Periodontology, 735 F.2d 1479, 1491-93 (D.C. Cir. 1984); United States Trotting Ass'n v. Chicago Downs Ass'n, 665 F.2d 781, 788-90 (7th Cir. 1981); Virginia Academy of Clinical Psychologists v. Blue Shield of Va., 624 F.2d 476, 484-85 (4th Cir. 1980), *cert. denied*, 450 U.S. 916 (1981); Hatley v. American Quarter Horse Ass'n, 552 F.2d 646, 652-53 (5th Cir. 1977).

[17]105 S. Ct. 2613 (1985).

[18]*Id.* at 2621. "Market power" is "the capacity to act other than as a perfectly competitive firm would;" it often results from having a large market share. P. AREEDA, *supra* note 15, at ¶ 201.

[19]105 S. Ct. at 2621.

[20]*Id.*

III. Hospital Staff Privileges

A. Overview of Staff Privileges

A health care provider must have staff privileges in order to admit his patients to a hospital and to care for them there.[21] A hospital's decision whether to grant these privileges is typically made by a committee of the medical staff, physicians who have privileges at the institution, by applying criteria in the hospital's by-laws.[22] This decision may be reviewed by the entire medical staff and is subject to approval by the hospital's board of directors or trustees.[23]

The Joint Commission on Accreditation of Hospitals (JCAH), a private body formed and run by physicians and hospitals, is responsible for accrediting most of the hospitals in this country.[24] The JCAH has established several categories of hospital privileges. These categories include "clinical privileges," whereby a provider may not admit patients to a hospital but he may provide treatment there, as well as privileges providing for varying levels of participation on the medical staff itself.[25] The most advantageous category for a practitioner is full membership on the medical staff, with its attendant admission privileges and voting rights in setting medical policy.

Whether an applicant is granted privileges is critical to him, both professionally and economically.[26] If certain tasks of his profession, such as surgical procedures, must be done in a hospital, the lack of privileges means that his range of practice is significantly curtailed. If he has no privileges and one of his patients needs treatment that can only be provided in a hospital, he must refer the patient to a provider with privileges and he may never get the patient back. Furthermore, if patients

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[21]Joint Comm'n on Accreditation of Hosps., Accreditation Manual for Hospitals, 1986 111 (1985).

[22]*Id.* at 101-02, 107. *See generally* M. Roemer & J. Friedman, Doctors in Hospitals 43-46, 225 (1971).

[23]Joint Comm'n on Accreditation of Hosps., *supra* note 21, at 101-02, 114; *see also* M. Roemer & J. Friedman, *supra* note 22.

[24]Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. Rev. 835, 839 (1983).

[25]For example, in addition to the "active medical staff," a hospital may establish an "associate medical staff," consisting of "physicians and dentists who are being considered for advancement to the active medical staff;" a "courtesy medical staff," with "privileges to admit and treat only an occasional patient;" and a "consulting medical staff" of physicians who are not in another category, but who come to the hospital to consult. Joint Comm'n on Accreditation of Hosps., Accreditation Manual for Hospitals 89-96 (1984); *see also* Quinn v. Kent Gen. Hosp., 617 F. Supp. 1226, 1231 (D. Del. 1985) (physician appointed to consulting staff challenged exclusion from active medical staff where only active medical staff could admit patients); Jost, *supra* note 24, at 873.

[26]Enders, *supra* note 3, at 737.

know the applicant cannot use a hospital, they may elect not to go to him at all.[27]

There has historically been some degree of conflict between physicians on the medical staff, concerned primarily that the hospital provides the facilities, support staff, and equipment the doctors need, and the hospital administration, concerned primarily with budgetary and efficiency matters.[28] Recent economic changes in the market for health and hospital services are likely to intensify this conflict with regard to admission privileges. There is currently a surplus of some types of physicians, which is expected to increase in the future.[29] The resulting increased competition for patients may lead physicians on staff to deny privileges to unwanted competitors.[30] In addition, the recent change to a prospective payment method for federal Medicare payments to hospitals has led to empty beds because hospitals are discharging patients earlier.[31] While hospitals may have an incentive to increase their medical staff to provide patients to fill the empty beds, hospitals must also appease the doctors already on staff to encourage them to admit more patients.[32] Finally, the development of preferred provider organizations (PPO's) promises to increase price competition among hospitals. One commentator predicts this will only increase tension between the medical staff and hospital administration as physicians respond to the increased competition by trying to close the staff while administrators want a larger staff to increase business.[33]

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[27]*See* Wolf v. Jane Phillips Episcopal-Memorial Medical Center, 513 F.2d 684, 686 (10th Cir. 1975).

[28]M. ROEMER & J. FRIEDMAN, *supra* note 22, at 283.

[29]Tarlov, *Shattuck Lecture—The Increasing Supply of Physicians, the Changing Structure of the Health Services System, and the Future Practice of Medicine*, 308 NEW ENG. J. MED. 1235, 1237-38 (1983).

[30]Spivey, *The Relation Between Hospital Management and Medical Staff Under a Prospective-Payment System*, 310 NEW ENG. J. MED. 984, 984 (1984).

[31]*Patients Are Leaving Hospitals Sooner and Sicker, Study Says*, 85 AM. J. NURSING 828 (1985). Under the new prospective payment method, Medicare pays a hospital for a specified number of days of care based on a patient's diagnostic category. If the patient's hospitalization lasts longer than predicted based on his diagnosis, the hospital is not paid for the extra days. Conversely, if the patient is sent home in fewer than the established number of days, the hospital still receives the predetermined amount. Therefore, there is an incentive for hospitals to discharge patients quickly. Havighurst, *Doctors and Hospitals: An Antitrust Perspective on Traditional Relationships*, 84 DUKE L.J. 1071, 1077 n.14 (1984).

[32]*See* Mechanic, *Some Dilemmas in Health Care Policy*, 59 MILBANK MEMORIAL FUND Q. 1, 4-5 (1981); Spivey, *supra* note 30.

[33]Spivey, *supra* note 30. *But see* Enders, *supra* note 3, at 738-39. A preferred provider organization is an arrangement whereby a group of doctors or hospitals contracts with an insurer or other purchaser of health care to provide services to insureds at set (usually discounted) fees. The disadvantage to the provider of the lower fees is offset by increased business from participating in the PPO. Built-in financial disincentives discourage patients

B. Non-Physicians and Hospital Privileges

Until 1985, the Joint Commission on Accreditation of Hospitals required that medical staff membership be restricted to physicians and dentists.[34] However, partially because of antitrust suits against the JCAH by non-physician groups categorically denied staff privileges,[35] the JCAH relaxed its criteria and now permits each hospital to decide for itself whether to grant staff privileges to independent non-physician health care providers.[36] This change may encourage non-physicians to apply for privileges and to sue under the antitrust laws if privileges are denied.

Several specific non-physician groups desire hospital privileges and have legally challenged privilege denials in the past. One such group is podiatrists. Podiatrists receive four years of graduate level education in the diagnosis and medical and surgical treatment of diseases of the foot and are licensed in all states.[37] Podiatrists seek hospital privileges because some complex podiatric surgical procedures can best be performed in a hospital or because surgical patients have chronic medical diseases and require close monitoring and observation available only in a hospital setting.[38] Podiatrists compete with orthopedic surgeons in the market for foot surgery.[39]

A major antitrust suit by a podiatrist who lost his hospital admitting and surgical privileges due to the previous JCAH restriction was *Levin*

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from seeking care from other than a "preferred provider." *See* AMERICAN HOSP. ASS'N, LEGAL DEVELOPMENTS REPORT NO. 4, STATE REGULATION OF PREFERRED PROVIDER ORGANIZATIONS: A SURVEY OF STATE STATUTES iv (1984).

[34]JOINT COMM'N ON ACCREDITATION OF HOSPS., *supra* note 25, at 89.

[35]*See, e.g.*, Wilk v. American Medical Ass'n, 719 F.2d 207 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984); Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965); Health Care Equalization Comm. of the Iowa Chiropractic Soc'y v. Iowa Medical Soc'y, 501 F. Supp. 970 (S.D. Iowa 1980); New York v. American Medical Ass'n, 1980-2 Trade Cas. (CCH) ¶ 63,456 (E.D.N.Y. 1980); *Ohio Charges Accreditation Association*, *supra* note 2. *See generally* AMERICAN HOSP. ASS'N, AN ANALYSIS OF THE REVISED MEDICAL STAFF STANDARDS OF THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS 1-2 (1984); Beardon, *JCAH Adopts Revised Medical Staff Standards*, 2 THE HEALTH LAWYER 4, 4 (1984); Jost, *supra* note 24, at 912. One report estimated the potential antitrust liability of the JCAH and other medical organizations named as defendants in four pending antitrust actions at over $300 million. *JCAH Is Weighing Wider Access to Staff Privileges in Hospitals*, 83 AM. J. NURSING 1260 (1983).

[36]*See* JOINT COMM'N ON ACCREDITATION OF HOSPS., *supra* note 21, at 101. *See generally* AMERICAN HOSP. ASS'N. *supra* note 35, at 2-13.

[37]Hollowell, *The Growing Legal Contest—Hospital Privileges for Podiatrists*, 23 ST. LOUIS U.L.J. 491, 492 & n.8 (1979).

[38]*See* Podell, *Issues in the Organization of Medical Care: An Illustrative Case Study—Podiatry in the United States*, 284 NEW ENG. J. MED. 586, 587 (1971).

[39]Skipper & Hughes, *Podiatry: Critical Issues in the 1980's*, 74 AM. J. PUB. HEALTH, 507, 507 (1984).

v. Doctors Hospital.[40] After Levin successfully joined the JCAH as a defendant,[41] the suit was settled out of court. As part of the settlement, the JCAH established a separate category of clinical privileges for podiatrists whereby, at the discretion of the individual hospital, a podiatrist and a physician could collaborate on admitting and treating a podiatric patient.[42] In the twenty years since *Levin*, podiatrists have succeeded in gaining some type of privileges at over fifty percent of the hospitals in this country.[43] However, two recent cases in which podiatrists lost antitrust challenges to the categorical denial of staff privileges attest to the continuing vitality of physicians' resistance to podiatrists obtaining hospital privileges.[44]

Clinical psychologists, who compete with physician psychiatrists in the market for psychotherapy and treatment of mental illness, seek hospital privileges to admit and treat patients experiencing acute emotional crises or patients requiring constant protection against self-harm.[45] Psychologists have been less successful than podiatrists in getting a foot in the door regarding hospital privileges.[46] The major psychologists' privileges case was instituted by the Attorney General of Ohio, who alleged that the categorical denial of staff privileges to psychologists foreclosed

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[40]233 F. Supp. 953 (D.D.C. 1964), *rev'd per curiam sub nom.* Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965).

[41]Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965).

[42]Hollowell, *supra* note 37, at 500-01 n.55.

[43]American Podiatric Medical Ass'n, Foot Care: A Major Product Line for Today's Competitive Hospital Marketplace 1 (1985).

[44]Kaczanowski v. Medical Center Hosp. of Vt., 612 F. Supp. 688 (D. Vt. 1985); Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685 (M.D.N.C. 1985), *aff'd*, 789 F.2d 278 (4th Cir. 1986). For earlier cases in which podiatrists challenged exclusion from hospitals on antitrust or constitutional grounds, see Shaw v. Hospital Auth. of Cobb County, 614 F.2d 946 (5th Cir.), *cert. denied*, 449 U.S. 955 (1980); Feldman v. Jackson Memorial Hosp., 571 F. Supp. 1000 (S.D. Fla. 1983), *aff'd mem.*, 752 F.2d 647 (11th Cir.), *cert. denied*, 105 S. Ct. 3504 (1985); Todd v. Physicians & Surgeons Community Hosp., 165 Ga. App. 656, 302 S.E.2d 378 (1983); Settler v. Hopedale Medical Found., 80 Ill. App. 3d 850, 400 N.E.2d 577 (1980); Davidson v. Youngstown Hosp. Ass'n, 19 Ohio App. 2d 246, 250 N.E.2d 892 (1969). *See also Hospital Must Consider Podiatrists for Privileges*, [July-Dec.] Antitrust & Trade Reg. Rep. (BNA) No. 1238, at 742 (Oct. 31, 1985) (podiatrists successfully challenged denial of privileges by invoking state antidiscrimination statute); 50 Fed. Reg. 41,693 (1985) (consent agreement proposed Oct. 11, 1985, to settle complaint by Federal Trade Commission that a hospital's and medical staff's restrictions of podiatrists' surgical privileges restrained competition in violation of section 5 of Federal Trade Commission Act).

[45]Tanney, *Hospital Privileges for Psychologists—A Legislative Model*, 38 Am. Psychologist 1232, 1233 (1983).

[46]*See* McGuire & Moore, *Private Regulation in Mental Health: The JCAH and Psychologists in Hospitals*, 7 L. & Hum. Behav. 235 (1983); Zaro, Batchelor, Ginsberg & Pallak, *Psychology and the JCAH: Reflections on a Decade of Struggle*, 37 Am. Psychologist 1342 (1982).

consumer choice in the market for mental health care and stabilized prices at non-competitive levels.[47] The case became moot, however, when the Ohio legislature enacted a statute that restricted hospital admission privileges to physicians.[48]

Another non-physician group interested in obtaining staff privileges is nurse-midwives.[49] Nurse-midwives are registered nurses who have completed six to twenty-four months of additional specialized training and who are certified to provide health care for women during all phases of the reproductive cycle and to deliver babies of women with low-risk pregnancies.[50] By statute, nurse-midwives must be supervised by physicians for some aspects of their practice.[51] In 1982, nurse-midwives delivered only 1.8 percent of the babies born in the United States, but this proportion was an eighty percent increase from 1976.[52] Nurse-midwives directly compete with obstetricians in the market for childbirth services. Legal battles involving hospital privileges for nurse-midwives have been reported in several states and the District of Columbia, although no antitrust case has yet been decided on the merits.[53]

The most recent group to challenge denial of privileges under the antitrust laws is nurse-anesthetists. Nurse-anesthetists are registered nurses who receive a minimum of two years of additional training in administering anesthesia.[54] Like nurse-midwives, they must work under physician supervision.[55] Historically, nurses were the primary group responsible for administering anesthesia in this country, and nurse-anesthetists are still responsible for more than fifty percent of anesthetic procedures.[56] Today, nurse-anesthetists' primary competitors are physician anesthesiologists, and in a market with an increasing supply of anesthesia providers, the competition is intense.[57]

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[47]*Ohio Charges Accreditation Association*, *supra* note 2.

[48]OHIO REV. CODE ANN. § 3727.06 (Page Supp. 1985).

[49]*See generally* Comment, *Hospital Privileges for Nurse-Midwives: An Examination Under Antitrust Law*, 33 AM. U.L. REV. 959 (1984).

[50]Adams, *Nurse-Midwifery Practice in the United States, 1982*, 74 AM. J. PUB. HEALTH 1267, 1267 (1984); Levy, Wilkinson & Marine, *Reducing Neonatal Mortality Rate with Nurse-Midwives*, 109 AM. J. OBSTETRICS & GYNECOLOGY 50, 51 (1971).

[51]Levy, Wilkinson & Marine, *supra* note 50, at 51; *see, e.g.*, CONN. GEN. STAT. ANN. § 20-86(b) (West Supp. 1986); N.J. STAT. ANN. § 45:10-8 (West 1978); OHIO REV. CODE ANN. § 4731.33 (Page 1977).

[52]Adams, *supra* note 50, at 1267, 1270.

[53]*See* Nurse Midwifery Assocs. v. Hibbett, 549 F. Supp. 1185 (M.D. Tenn. 1982); *CNM's Seek Test of Right to Compete with MD's*, 85 AM. J. NURSING 599 (1985); *CNM's Pursue Admitting Privileges*, 83 AM. J. NURSING 1261 (1983).

[54]Adams, *Nurse Anesthetist Clarifies Group's Responsibilities*, Am. Med. News, May 10, 1985, at 6, col. 1.

[55]*Id.*; *see, e.g.*, OHIO REV. CODE ANN. § 4731.35 (Page 1977).

[56]Adams, *supra* note 54; *CRNA's Battle a Trend to Phase Out Hospital Jobs*, 84 AM. J. NURSING 376, 386 (1984) [hereinafter *CRNA's Battle*].

[57]*CRNA's Battle*, *supra* note 56, at 386, 390.

Neither nurse-anesthetists nor physician anesthesiologists actually admit patients to a hospital. They generally work under a contractual arrangement to provide anesthesia to surgical patients.[58] Consequently, the conflict has not been over staff privileges per se, but over potential anticompetitive abuses where contractual arrangements have been changed to replace nurse-anesthetists with physician anesthesiologists.[59] In Maine, the state attorney general accused anesthesiologists who attempted to close a nurse-anesthetist training program of violating antitrust law.[60] The physicians entered into a consent decree enjoining them from raising prices, negotiating exclusive contracts, and interfering with the employment or training of nurse-anesthetists.[61] In West Virginia, the state attorney general also alleged antitrust violations where two hospitals changed their staff by-laws to block nurse-anesthetists from obtaining staff privileges, and also reached a settlement in which the anesthesiologists involved would not raise prices, enter into exclusive contracts, or jointly participate in any privileges decision regarding nurse-anesthetists.[62] Finally, in a case from California, the Ninth Circuit declared that nurse-anesthetists compete with physician anesthesiologists despite a state statutory requirement that nurse-anesthetists be supervised by physicians, thus permitting a nurse-anesthetist barred from hospital practice to proceed with his antitrust suit.[63]

Chiropractors are another group seeking access to hospitals, although chiropractors may not actually compete with physicians. At least one study suggests consumers do not view chiropractors' services as a substitute for physicians'.[64] Nevertheless, chiropractors have been challenging exclusionary behavior by the medical establishment for years.[65] Regarding

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[58]*See* Adams, *supra* note 54.

[59]*See CRNA's Battle*, *supra* note 56, at 376-90.

[60]State v. Anesthesia Prof. Ass'n, 1984-2 Trade Cas. (CCH) ¶ 66,081 (Me. Super. Ct. 1984).

[61]*Id. See generally Maine Aims AT Blow at MD's and Saves the Day for CRNA's*, 85 AM. J. NURSING 600 (1985) (reports background of the litigation).

[62]*Anesthesiologists Will Hold Down Prices Under Settlement with Attorney General*, [Jan.-June] Antitrust & Trade Reg. Rep. (BNA) No. 1258, at 551 (March 27, 1986).

[63]Bhan v. NME Hosp., Inc., 772 F.2d 1467 (9th Cir. 1985).

[64]Yesalis, Wallace, Fisher & Tokheim, *Does Chiropractic Utilization Substitute for Less Available Medical Services?*, 70 AM. J. PUB. HEALTH 415 (1980).

[65]*See* Wilk v. American Medical Ass'n, 719 F.2d 207 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984); Ballard v. Blue Shield of S. W. Va., 543 F.2d 1075 (4th Cir. 1976), *cert. denied*, 430 U.S. 922 (1977); Aasum v. Good Samaritan Hosp., 542 F.2d 792 (9th Cir. 1976); Spears Free Clinic & Hosp. for Poor Children v. Cleere, 197 F.2d 125 (10th Cir. 1952); Chiropractic Coop. Ass'n of Mich. v. American Medical Ass'n, 617 F. Supp. 264 (E.D. Mich. 1985); Slavek v. American Medical Ass'n, 1982-1 Trade Cas. (CCH) ¶ 64,509 (E.D. Pa. 1982); Ballard v. Blue Shield of S. W. Va., 529 F. Supp. 71 (S.D. W. Va. 1981); Health Care Equalization Comm. of the Iowa Chiropractic Soc'y v. Iowa Medical Soc'y, 501 F. Supp. 970 (S.D. Iowa 1980); New York v. American Medical Ass'n,

hospital access, chiropractors do not necessarily want admitting privileges, but merely the ability to refer patients to a hospital's laboratory or x-ray facilities as an aid in diagnosis.[66] In the past, the JCAH has warned hospitals that cooperating with chiropractors even to this extent might threaten the hospital's accreditation.[67] In light of the recent relaxation of JCAH standards for privileges,[68] however, each individual hospital may now apparently decide whether to accommodate chiropractors. In general, chiropractors have not fared well in their legal efforts to gain access to hospitals,[69] although suits by chiropractors against medical associations may be partially responsible for the change in JCAH standards.

IV. Hospital Privilege Denials as a Group Boycott

As a result of United States Supreme Court decisions in the 1970's and early 1980's, health care providers can challenge the denial of hospital privileges under the antitrust laws. In *Hospital Building Co. v. Trustees of Rex Hospital*[70] and *McLain v. Real Estate Board of New Orleans*,[71] the Court relaxed its definition of interstate commerce, so that a plaintiff's showing that the challenged restraint affects the purchase of supplies out-of-state or the billing of out-of-state insurers is enough to satisfy the Sherman Act's interstate commerce requirement.[72] More significantly,

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1980-2 Trade Cas. (CCH) ¶ 63,456 (E.D.N.Y. 1980); Kentucky Ass'n of Chiropractors v. Jefferson County Medical Soc'y, 549 S.W.2d 817 (Ky. 1977); New Jersey Chiropractic Soc'y v. Radiological Soc'y of N.J., 156 N.J. Super. 365, 383 A.2d 1182 (1978); Boos v. Donnell, 421 P.2d 644 (Okla. 1966).

[66]*See* Kissam, Webber, Bigus & Holzgraefe, *Antitrust and Hospital Privileges: Testing the Conventional Wisdom*, 70 Calif. L. Rev. 595, 675 (1982) [hereinafter Kissam & Webber]; Note, *Health Professionals' Access to Hospitals: A Retrospective and Prospective Analysis*, 34 Vand. L. Rev. 1161, 1194 (1981).

[67]Wilk v. American Medical Ass'n, 719 F.2d 207, 214 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984); *see also* Aasum v. Good Samaritan Hosp., 395 F. Supp. 363, 370-71 (D. Ore. 1975), *aff'd*, 542 F.2d 792 (9th Cir. 1976).

[68]*See supra* notes 35-36 and accompanying text.

[69]*See, e.g.*, Aasum v. Good Samaritan Hosp., 395 F. Supp. 363 (D. Ore. 1975), *aff'd*, 542 F.2d 792 (9th Cir. 1976); Boos v. Donnell 421 P.2d 644 (Okla. 1966); *cf.* Kentucky Ass'n of Chiropractors v. Jefferson County Medical Soc'y, 549 S.W.2d 817 (Ky. 1977) (chiropractors not permitted to use services of medical laboratories).

[70]425 U.S. 738 (1976).

[71]444 U.S. 232 (1980).

[72]*Hospital Bldg. Co.*, 425 U.S. at 744; *McLain*, 444 U.S. at 242, 245. There is conflict among the federal circuit courts of appeal as to just how much *McLain* relaxed the definition, i.e. as to whether a plaintiff may show merely that a defendant's business activities in general affect interstate commerce or whether a plaintiff must show a nexus between the challenged restraint and interstate commerce. *See* Shahawy v. Harrison, 778 F.2d 636 (11th Cir. 1985); Seglin v. Esau, 769 F.2d 1274 (7th Cir. 1985); Hayden v. Bracy, 744 F.2d 1338 (8th Cir. 1984); Cardio-Medical Assocs. v. Crozer-Chester Medical Center, 721 F.2d 68 (3d Cir. 1983); Furlong v. Long Island College Hosp., 710 F.2d 922

in *Goldfarb v. Virginia State Bar*[73] and in *Arizona v. Maricopa County Medical Society*,[74] the Court made it clear that professionals, including physicians, are not exempt from the antitrust laws.[75] These changes cleared the way for a deluge of antitrust suits challenging privilege denials, many of which were brought by individual physicians.[76] Because an excluded privileges applicant competes with physicians on the hospital's medical staff, the denial of hospital privileges can be characterized as a group boycott. The staff's recommendation to deny or terminate privileges is a joint decision by competitors that deprives the applicant of access to the hospital, a resource essential to his ability to compete.[77]

Because a group boycott is a violation of section one of the Sherman Act, a critical issue in a hospital privileges suit brought on a group boycott theory is the existence of a conspiracy or concerted action by competitors. Some defendants have asserted that the denial of privileges resulted from merely unilateral action by the hospital; thus, there was not the combination or conspiracy required for a section one violation.[78] However, although the hospital board makes the final decision on whether to grant privileges, hospital boards almost always defer to the medical expertise of physicians and agree with the medical staff's or staff committee's recommendation.[79] According to one federal district court, the individual physicians on the staff or on the reviewing committee are more than the mere agents of the hospital in making this recommendation because the doctors have a personal economic interest in the outcome

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(2d Cir. 1983); Mishler v. St. Anthony's Hosp. Sys., 694 F.2d 1225 (10th Cir. 1981); Crane v. Intermountain Health Care, Inc., 637 F.2d 715 (10th Cir. 1981) (on reh'g en banc); Capili v. Shott, 620 F.2d 439 (4th Cir. 1980).

[73]421 U.S. 773 (1975).

[74]457 U.S. 332 (1982).

[75]*Goldfarb*, 421 U.S. at 787-88; *Maricopa*, 457 U.S. at 348-49.

[76]*Attempts to Gain Access to Hospitals Are Prevalent in Health Care Actions*, [Jan.-June] Antitrust & Trade Reg. Rep. (BNA) No. 1150, at 187 (Feb. 2, 1984). In October 1986, Congress effectively eliminated antitrust suits by individual physicians by providing immunity from damages liability for peer review committees, their members, and the hospital where restrictions in clinical privileges are based on review of a physician's competence or professional conduct. Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, tit. IV. The statutory definition of immunized conduct refers only to "individual physician[s]," *id.* § 431(9), so presumably the statute does not cover applications for hospital privileges by non-physicians, nor does it preclude a physician seeking injunctive relief.

[77]*See supra* notes 13-15 and accompanying text.

[78]*See* Weiss v. York Hosp., 745 F.2d 786, 814-17 (3d Cir. 1984), *cert. denied*, 105 S. Ct. 1777 (1985); Quinn v. Kent Gen. Hosp., 617 F. Supp. 1226, 1242 (D. Del. 1985); Feldman v. Jackson Memorial Hosp., 571 F. Supp. 1000, 1009 (S.D. Fla. 1983), *aff'd mem.*, 752 F.2d 647 (11th Cir. 1985), *cert. denied*, 105 S. Ct. 3504 (1985); Williams v. Kleaveland, 534 F. Supp. 912, 920 (W.D. Mich. 1981).

[79]Redisch, *Physician Involvement in Hospital Decision Making*, in HOSPITAL COST CONTAINMENT 217, 220-21 (M. Zubkoff, I. Raskin & R. Hanft eds. 1978).

of the privileges decision.[80] Therefore, the board's approval of this recommendation does not immunize the staff's action from antitrust scrutiny. In *Weiss v. York Hospital*,[81] the Third Circuit held that as a matter of law, a medical staff is a combination of competitors.[82] This court also noted the individual economic interest of staff members in the outcome of a privileges decision.[83] According to this view, the potentially illegal conspiracy is not between the staff and the hospital, but within the staff itself.

The absence on the reviewing committee of a direct competitor of an applicant should not mislead a court to conclude that there was no anticompetitive conduct.[84] Commentators have noted the immense power of the referral network among physicians.[85] Because physician specialists depend on their physician colleagues for patient referrals and for coverage on days off, there is great incentive for physicians to conform to their colleagues' wishes.[86] Peer pressure subtly exerted on the members of a reviewing committee could easily induce them to deny privileges to their colleagues' unwanted competitors.

Although a group boycott can be a per se antitrust offense,[87] most courts faced with hospital privileges cases have applied the rule of reason, on several bases. One basis is that hospital privileges decisions are a form of industry self-regulation.[88] Because industry self-regulation can have significant procompetitive benefits, whether a particular restraint is unreasonable can only be determined after detailed analysis under the rule of reason.[89] Also, although the Supreme Court in *Maricopa* made

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[80]Robinson v. Magovern, 521 F. Supp. 842, 907 (W.D. Pa. 1981), *aff'd mem.*, 688 F.2d 824 (3rd Cir.), *cert denied*, 459 U.S. 971 (1982).

[81]745 F.2d 786 (3rd Cir. 1984), *cert denied*, 105 S. Ct. 1777 (1985).

[82]*Id.* at 814.

[83]*Id.* at 815-16.

[84]Havighurst, *supra* note 31, at 1116-17.

[85]*See, e.g.*, E. Freidson, Professional Dominance—The Social Structure of Medical Care 72, 99, 190 (1970).

[86]A clear example of how physicians can influence their colleagues' behavior without overt coercion appears in Feminist Women's Health Center v. Mohammad, where an obstetrician described how peer pressure induced him to sever his relations with an abortion clinic. 586 F.2d 530, 536-37 (5th Cir. 1978), *cert. denied*, 444 U.S. 924 (1979).

[87]Silver v. New York Stock Exch., 373 U.S. 341, 347-48 (1963); Klor's v. Broadway-Hale Stores, 359 U.S. 207, 212 (1959); *see also* Weiss v. York Hosp., 745 F.2d 786 (3d Cir. 1984), *cert. denied*, 105 S. Ct. 1777 (1985) (denial of privileges to osteopaths held to be per se illegal group boycott).

[88]*See, e.g.*, Vuciecevic v. MacNeal Memorial Hosp., 572 F. Supp. 1424, 1428 (N.D. Ill. 1983); *cf.* Kreuzer v. American Academy of Periodontology, 735 F.2d 1479, 1491 (D.C. Cir. 1984) (rule of reason appropriate for evaluating professional association's exclusion of dentist based on application of standards).

[89]*See, e.g.*, Silver v. New York Stock Exch., 373 U.S. 341, 348-49 (1963) (rule of reason may be appropriate approach where proper procedures have been followed in stock exchange self-regulation under Securities Exchange Act); Hatley v. American Quarter Horse

it clear that per se rules may apply to learned professions,[90] dicta in this and other Supreme Court decisions suggest that the rule of reason is the proper approach when restraints of trade by a profession are premised on public service or ethical norms.[91] A denial of privileges because the applicant fails to meet a quality standard has such a premise.[92] Some courts have used the rule of reason because the judiciary lacks experience applying antitrust laws to the health care industry.[93] These courts are wary of per se condemnation of a particular industry practice until they can be more confident that the practice will almost always be anticompetitive.

Finally, despite the Supreme Court's recent statement in *Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co.*[94] that the per se rule may apply to a group boycott if the defendant has market power,[95] where the defendant hospital in a privileges case has market power, a trial court might use the rule of reason. Dicta in *Northwest Stationers* suggesting that "plausible arguments that [the restraints] were intended to enhance overall efficiency and make markets more competitive"[96] may weaken the per se rule's presumption of anticompetitive effect and make the rule of reason the appropriate judicial

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Ass'n, 552 F.2d 646, 652 (5th Cir. 1977) (rule of reason appropriate where group boycott alleged in context of sports industry self-regulation); *see also* Ponsoldt, *The Application of Sherman Act Antiboycott Law to Industry Self-Regulation: An Analysis Integrating Nonboycott Sherman Act Principles*, 55 S. CAL. L. REV. 1, 33-34 (1981).

[90]457 U.S. at 348-49.

[91]*Id.* (per se rule applicable where doctors' conduct "not premised on public service or ethical norms"); National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 696 (1978) ("professional services may differ significantly from other business services, and, accordingly, the nature of the competition in such services may vary. Ethical norms may serve to regulate and promote this competition, and thus fall within the Rule of Reason."); Goldfarb v. Virginia State Bar, 421 U.S. 773, 788-89 n.17 (1975) ("The public service aspect, and other features of the professions, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently."); *see also* Federal Trade Comm'n v. Indiana Fed'n of Dentists, 106 S. Ct. 2009, 2018 (1986) ("we have been slow to condemn rules adopted by professional associations as unreasonable *per se*").

[92]*See, e.g.*, Weiss v. York Hosp., 745 F.2d 786, 820 (3d Cir. 1984), *cert. denied*, 105 S. Ct. 1777 (1985) (per se rule applied because "defendants have offered no 'public service or ethical norm' rationale"); Pontius v. Children's Hosp., 552 F. Supp. 1352, 1369-70 (W.D. Pa. 1982); *see also* Chiropractic Coop. Ass'n of Mich. v. American Medical Ass'n, 617 F. Supp. 264, 269 (E.D. Mich. 1985) (defendant physicians' assertion that exclusion of chiropractors was motivated by quality of care invokes rule of reason).

[93]Vuciecevic v. MacNeal Memorial Hosp., 572 F. Supp. 1424, 1427 (N.D. Ill. 1983); Pontius v. Children's Hosp., 552 F. Supp. 1352, 1368 (W.D. Pa. 1982); Everhart v. Jane C. Stormont Hosp., 1982-1 Trade Cas. (CCH) ¶ 64,703, 73,897 (D. Kans. 1982).

[94]105 S. Ct. 2613 (1985).

[95]*Id.* at 2621.

[96]*Id.* at 2620.

approach. Particularly in rural areas, a hospital may have market power simply because it is the only hospital in a county. Applying the per se rule when rural hospitals deny staff privileges while applying the rule of reason to the same practice by urban hospitals would be illogical and could deny rural hospitals necessary discretion to qualitatively screen individual applicants, for fear of per se antitrust liability.[97] Supreme Court dicta in an earlier hospital privileges case emphasizing "the hospital's unquestioned right to exercise some control over the identity and the number of doctors to whom it accords staff privileges"[98] further support application of the rule of reason to a hospital privileges case, even where the defendant hospital has market power.

V. Quality of Care as a Defense

A. *Overview*

Under the rule of reason, a defendant may not justify a privileges denial merely by asserting that restricting hospital privileges to the most highly-qualified practitioners promotes the public health or welfare.[99] In *National Society of Professional Engineers v. United States*,[100] the Supreme Court emphasized that the rule of reason permits only justifications based on the procompetitive effects of an alleged restraint.[101] The Court stated that to permit an antitrust defense based on protecting the public welfare would be "tantamount to a repeal"[102] of the Sherman Act and suggested that such an argument is more properly directed to the legislature.[103]

The Court recently repeated this position in *Federal Trade Commission v. Indiana Federation of Dentists*.[104] The Federal Trade Commission had found that a collective refusal by a group of dentists to submit dental x-rays to insurers to enable the insurers to assess the appropriateness of care was an unreasonable restraint of trade.[105] The dentists attempted to justify their boycott by asserting that they were protecting the quality of dental care.[106] The Supreme Court rejected this argument and reaffirmed its position in *Professional Engineers* that quality of service considerations unrelated to enhancing competition are not available as a justification under the rule of reason.[107]

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[97]*See* Pontius v. Children's Hosp., 552 F. Supp. 1352, 1370, 1377 (W.D. Pa. 1982).
[98]Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 30 (1984) (dictum).
[99]Havighurst, *supra* note 31, at 1095; Kissam & Webber, *supra* note 66, at 646.
[100]435 U.S. 679 (1978).
[101]*Id.* at 688-92, 694.
[102]*Id.* at 695.
[103]*Id.* at 689-90.
[104]106 S. Ct. 2009 (1986).
[105]*Id.* at 2014-15.
[106]*Id.* at 2015, 2020.
[107]*Id.* at 2020-21. The Court hinted that there might be circumstances where quality

In *Wilk v. American Medical Association*,[108] a case in which chiropractors alleged antitrust violations in various exclusionary acts by organized medicine, the Seventh Circuit also emphasized that under the rule of reason, the effect of the challenged restraint on competition is the "critical and sole factor"[109] in determining whether a practice is illegal. Nevertheless, the Seventh Circuit, citing Supreme Court dicta regarding the application of the antitrust laws to professions, fashioned a new rule of reason defense for physicians where their exclusionary conduct is motivated by an ethical concern for their patients' well-being.[110] Commentators have been critical of this judicial creation of a special rule, pointing out that the Supreme Court's suggestions that the antitrust laws might operate differently for the service and ethical aspects of a profession can be satisfied by a special sensitivity to the unusual features of competition in professional markets.[111] Such a unique rule for physicians threatens to undermine the basic premise of the rule of reason, that effect on competition is the sole yardstick for legality, and threatens to legitimize professional usurpation of the legislative function of deciding what is in the public interest.[112]

Under the rule of reason, an exclusion based on quality of care is defensible, however, because quality is a major competitive variable in the health care industry. Because third-party insurers pay such a large proportion of health care bills, patients are relatively unconcerned about price when they purchase health services, leading to minimal price competition among physicians or hospitals.[113] Quality, instead of price, is a major factor patients and physicians use to select a hospital.[114] Therefore, where an exclusion improves the overall quality of a hospital, the restriction is procompetitive and quality of care may be asserted as a defense.[115]

Where non-physicians have been excluded, quality of care as a justification has arisen primarily in cases involving podiatrists and chi-

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of patient care could justify a restraint of trade. *Id.* at 2021. However, its focus here seems to be on situations where quality relates to ethical grounds or is otherwise "non-competitive." In a hospital privileges context, because hospitals compete with each other largely on the basis of quality, such a "loophole" in the rule of reason is unnecessary. *See infra* notes 113-15 and accompanying text.

[108]719 F.2d 207 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984).

[109]*Id.* at 225.

[110]*Id.* at 226-27 (citing *Professional Engineers*, 435 U.S. at 696; Goldfarb v. Virginia State Bar, 421 U.S. 773, 787 n.17 (1975)).

[111]Kissam, *Antitrust Boycott Doctrine*, 69 Iowa L. Rev. 1165, 1214-15 (1984).

[112]*Id.*; *see also* Havighurst, *supra* note 31, at 1103-04 n.101.

[113]Salkever, *Competition Among Hospitals*, in Competition in the Health Care Sector: Past, Present, and Future 191, 201 (1978).

[114]*Id.*

[115]*See, e.g.*, Dos Santos v. Columbus-Cuneo-Cabrini Medical Center, 684 F.2d 1346, 1355 (7th Cir. 1982); Pontius v. Children's Hosp., 521 F. Supp. 1352, 1365 (W.D. Pa. 1982).

ropractors,[116] although a similar rationale could apply to barring psychologists, nurse-midwives and nurse-anesthetists. The essence of this defense in a group context is that because physicians are the only group trained and licensed to independently diagnose and treat the whole person, only physicians should have hospital privileges.[117] Granting privileges to less qualified providers would threaten the overall quality of care in the institution; thus, the exclusion is procompetitive.

B. Judicial Approaches to Quality of Care as a Defense

Courts have taken a variety of approaches in evaluating quality of care as a procompetitive justification for denying hospital privileges to individual physicians or to groups of non-physicians. Some courts have almost totally deferred to medical authority, labeling the privileges decision professional rather than commercial. For example, in *Hackett v. Metropolitan General Hospital*,[118] a case brought by an individual physician under state antitrust law, the court, using federal antitrust concepts, stated, "[E]ven when serious anticompetitive effects exist[,] . . . professional decision-making relative to the quality or efficiency of health care should not be subject to antitrust constraints and, therefore, impeded."[119] Similarly, in a suit by podiatrists challenging a categorical denial of hospital privileges, a federal district court granted a summary judgment for defendant hospitals, finding in the record "nothing by way of the Sherman Act to call upon the courts to intrude upon a responsibility reserved to medical decision-makers."[120] In addition to deviating from the rule of reason's mandate that the proper judicial focus is on the impact on competition, this approach ignores the fact that privileges decisions have both professional and commercial aspects and, in some cases, could be economic decisions disguised as professional.[121]

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[116]*See* Wilk v. American Medical Ass'n, 719 F.2d 207 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984); Chiropractic Coop. Ass'n of Mich. v. American Medical Ass'n, 617 F. Supp. 264 (E.D. Mich. 1985); Kaczanowski v. Medical Center Hosp. of Vt., 612 F. Supp. 688 (D. Vt. 1985); Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685 (M.D.N.C. 1985), *aff'd*, 789 F.2d 278 (4th Cir. 1986).

[117]*See, e.g.*, Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685, 687 (M.D.N.C. 1985), *aff'd*, 789 F.2d 278 (4th Cir. 1986).

[118]465 So. 2d 1246 (Fla. Dist. Ct. App. 1985).

[119]*Id.* at 1252 n.3. This case defies easy categorization. The opinion approvingly cites a variety of approaches which, when blended, become very deferential.

[120]Kaczanowski v. Medical Center Hosp. of Vt., 612 F. Supp. 688, 697 (D. Vt. 1985); *see also* Levin v. Doctors Hosp., 233 F. Supp. 953, 954-55 (D.D.C. 1964), *rev'd per curiam sub nom.* Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965).

[121]Although not a hospital privileges case, Federal Trade Commission v. Indiana Federation of Dentists, 106 S. Ct. 2009 (1986), illustrates this possibility. In this case, dentists' assertions that their boycott of insurers was aimed at protecting the quality of

Other courts have looked to whether the exclusionary decision was made in good faith or was not arbitrary or capricious. For example, the federal district court in *Williams v. Kleaveland*,[122] a case involving an individual physician, invoked the professional-commercial distinction noted above and recognized a good faith defense, based on a bona fide concern for the public welfare.[123] A similar standard was used in a podiatrist's case in which the court granted a summary judgment for the defendant based on a "good faith judgment that high quality care requires that surgery . . . only be performed by physicians educated and trained to treat the whole person."[124] The court failed to consider the denial's impact on competition, although the court said it was applying the rule of reason.[125]

A third judicial approach has been to require a mere rational relation between the decision to exclude and quality of care. The court in *Kaczanowski v. Medical Center Hospital of Vermont*,[126] a podiatrists' case, thought that "common sense dictates that the use of sensitive medical instruments, which may engage highly technical diagnostic equipment . . . should not be entrusted to applicants who fail to meet a high level of advanced medical training."[127] The court did not address the facts that the plaintiff podiatrists had spent several years in professional school learning how to use the sensitive instruments and that the state legislature had decided it was proper for podiatrists to perform the surgical procedures at issue.[128]

Some courts have applied a higher level of scrutiny and required that a quality rationale for denial of privileges or other exclusionary conduct in a health care context be objectively reasonable. In *Feminist Women's Health Center v. Mohammad*,[129] the defendants were charged with a group boycott and other antitrust violations in persuading phy-

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dental care were substantially undermined by statements of a boycott leader that "We are fighting an economic war . . . . The name of the game is money." *Id.* at 2013 n.1.

[122]534 F. Supp. 912 (W.D. Mich. 1981).

[123]*Id.* at 920.

[124]Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685, 687 (M.D.N.C. 1985), *aff'd*, 789 F.2d 278 (4th Cir. 1986).

[125]*Id.*

[126]612 F. Supp. 688 (D. Vt. 1985).

[127]*Id.* at 697. *See generally* Havighurst, *supra* note 31, at 1133-36, recommending a rational basis test for privileges denials based on quality maintenance, absent market power or a violation of section two of the Sherman Act. This recommendation is premised on the hospital's ultimate accountability to consumers for its business decisions. Such a premise may be questionable in light of the hospital's greater responsiveness to physicians than to consumers. *See infra* notes 162-65 and accompanying text.

[128]*See* VT. STAT. ANN. tit. 7, § 321 (1975); *see also supra* note 37 and accompanying text.

[129]586 F.2d 530 (5th Cir. 1978), *cert. denied*, 444 U.S. 924 (1979).

sicians not to work at an abortion clinic. Reversing (on other grounds) a summary judgment for the defendants, the Fifth Circuit stated that under the rule of reason, the tests for evaluating a defense based on maintenance of professional standards are "the genuineness of the defendants' justification, the reasonableness of the standards themselves, and the manner of their enforcement."[130] In *Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia*,[131] the Fourth Circuit found that a requirement that third-party payment for psychologists' services be billed through a physician was patently unreasonable as a quality assurance measure because it permitted supervision by any physician, not just those knowledgeable about mental illness.[132] The court noted that "we are not inclined to condone anticompetitive conduct upon an incantation of 'good medical practice.' "[133]

In *Pontius v. Children's Hospital*,[134] a federal district court established the test under the rule of reason for evaluating termination of an individual physician's hospital privileges as "valid reasons supported by substantial evidence."[135] Because evaluating individual competence is largely subjective, the court stated it would not attempt to decide whether the privileges committee was correct, but would make sure there was substantial evidence to support the decision.[136] Perceptively noting a difference between exclusion of an individual and exclusion of a group of physicians, the court suggested that the validity of excluding a group on a quality basis is more capable of objective evaluation.[137] Although the court used the example of a categorical exclusion of a group of physicians from a specific medical school, exclusion of a group of non-physicians on a quality basis should be amenable to the same objective evaluation.

Finally, commentators and at least one court have advocated a "purpose-based rule of reason," requiring a dominant anticompetitive purpose for a denial of privileges to violate the Sherman Act.[138] One difficulty with purpose as the determinative criterion is that a hospital

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[130]*Id.* at 547.

[131]624 F.2d 476 (4th Cir. 1980), *cert. denied*, 450 U.S. 916 (1981).

[132]*Id.* at 485.

[133]*Id.* On remand, however, the federal district court found that determining a remedy for the boycotted psychologists had become a moot issue because of a Virginia Supreme Court decision that the state statute under which the plaintiff psychologists were demanding insurance reimbursement was unconstitutional. 501 F. Supp. 1232 (E.D. Va. 1980) (citing Blue Cross of Va. v. Commonwealth, 221 Va. 349, 269 S.E.2d 827 (1980)).

[134]552 F. Supp. 1352 (W.D. Pa. 1982).

[135]*Id.* at 1372.

[136]*Id.* at 1372-73.

[137]*Id.* at 1370-71.

[138]Hackett v. Metropolitan Gen. Hosp., 465 So. 2d 1246, 1255-57 (Fla. Dist. Ct. App. 1985); Kissam & Webber, *supra* note 66, at 660-62.

staff might have mixed purposes for a particular privileges denial or might assert a purpose to maintain the quality of care while the covert purpose is to suppress competition. Uncovering the true or dominant purpose will necessarily require a lengthy trial.[139] A second problem with this approach is that it is inconsistent with the rule of reason's primary focus on anticompetitive effect. According to Justice Brandeis' classic statement of the rule of reason in *Chicago Board of Trade v. United States*,[140] "[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition."[141] Justice Brandeis explained that a court may consider the purpose of the restraint, "not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences."[142] Thus, while purpose is relevant, it is not determinative.[143]

VI. Differences Between Denial of Privileges to an Individual and to a Group

In general, the lower courts have attempted to find a way to "guard against . . . anticompetitive abuses without disrupting the legitimate interests of hospitals and medical staffs in providing efficient and high quality medical care."[144] Except for the court in *Pontius v. Children's Hospital*, however, these courts have not clearly distinguished between denial of hospital privileges to individual physicians and denial to groups of non-physicians and have, therefore, applied the same variety of levels of scrutiny to both types of cases. There are at least four fundamental differences between denial of privileges to an individual and to a group: differences in the substantive validity of the quality rationale for exclusion, in the operation of due process, in procompetitive justifications, and in anticompetitive effects. Because of these distinctions, denial of privileges to a group merits antitrust scrutiny beyond a mere rational relation or good faith standard.

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[139]Havighurst, *supra* note 31, at 1109-10.

[140]246 U.S. 231 (1918).

[141]*Id.* at 238.

[142]*Id.*

[143]*See also* NCAA v. Board of Regents of the Univ. of Okla., 468 U.S. 85, 101 n.23 (1984) ("It is . . . well-settled that good motives will not validate an otherwise anticompetitive practice."); Kreuzer v. American Academy of Periodontology, 735 F.2d 1479, 1492-93 (D.C. Cir. 1984) (effect, and not intent, is controlling factor in a rule of reason inquiry); Ponsoldt, *supra* note 89, at 63 (lower courts often give great weight to defendants' intent despite Supreme Court declarations that intent is not controlling).

[144]Kissam & Webber, *supra* note 66, at 597.

A. Differences in the Substantive Validity of the Quality Justification

In contrast to a quality of care justification for denying privileges to an individual physician, there are inherent weaknesses in a quality rationale when applied to exclude a group of non-physicians. Although physicians are probably best qualified to assess a fellow physician's skill, training, and experience, they are not necessarily experts about the capabilities of allied health practitioners. Members of the medical staff may have little experience with or knowledge about the group being excluded. For example, only twenty-seven percent of physicians questioned in one study knew that podiatrists receive four years of graduate level podiatry education in addition to undergraduate studies.[145] Most physicians underestimated the extent of podiatry training.[146] There may be reason to question the validity of physicians' opinions of podiatric care if physicians lack even basic knowledge about podiatrists' education. Furthermore, physicians' evaluations of the quality of care rendered by non-physicians may be biased by the physicians' professional ego.[147] Because the training and experience of doctors may lead them to believe in their own superiority, their ability to judge objectively the competence of a group with different or less training may be distorted.[148]

There are also inherent weaknesses in the argument that allied groups should not obtain privileges because they are not qualified to treat the whole person.[149] Non-physicians do not necessarily want to treat the whole person; they want only to provide professional care within the scope of their licenses, whether it be care of the feet or the psyche.[150] As long as physicians are readily available to treat health problems beyond the scope of the non-physician's expertise, there is no reason to exclude the non-physician. Also, many physician specialists might fail to measure up to this "whole person" criterion. For example, a physician who has specialized in psychiatry for many years may no longer be competent to regulate insulin dosages in a newly diagnosed diabetic and would, as a matter of course, seek consultation from a more qualified physician. In an era of increasing specialization, there may be few health

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[145]Dixon, *Hospital Privileges for Podiatrists*, 24 HOSP. & HEALTH SERVICES AD. 63, 74 (1979).

[146]*Id.*

[147]*Cf.* Kissam & Webber, *supra* note 66, at 608 ("the professional pride of physicians often will be at stake . . . particularly when nonphysicians apply for privileges.").

[148]E. FREIDSON, *supra* note 85, at 146-58.

[149]*See* Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685, 687 (M.D.N.C. 1985), *aff'd.*, 789 F.2d 278 (4th Cir. 1986) (court accepted this argument and upheld denial of privileges to podiatrists).

[150]*Cf.* Dolan, *Antitrust Law and Physician Dominance of Other Health Practitioners*, 4 J. HEALTH POL. POL'Y & L. 675, 679 (1980).

care providers who are truly qualified to treat the whole person.[151] Finally, this "whole person" argument is weakened by the fact that hospital privileges were available to dentists even under the pre-1985 JCAH standards.[152] Dentists clearly are not trained to treat the whole person, but neither do they compete with physicians as directly as the excluded non-physician groups do.

Additionally, denying an entire professional group the opportunity to provide services for which it was trained and licensed has the effect of partially negating the licensure law. The courts have clearly declared that a license does not automatically give an individual the right to practice in any hospital.[153] A state licensure law is, however, a legislative determination that in general, people with the requisite training and knowledge can safely provide whatever service they are licensed to provide.[154] A hospital's denial of privileges to an entire licensed group on a quality basis is, in effect, a declaration that despite the legislature's judgment, no one with that particular license is competent to provide that service. The courts have been hostile to industry self-regulation that is so extensive that the industry acts as a private government and threatens to usurp the legislature's prerogative of determining what is in the public interest.[155]

A quality rationale for excluding a group may be further flawed if research demonstrates the safety or effectiveness of treatment by non-physicians. Although there are few such studies of patient-outcomes, an assertion that an allied health group gives inferior care is inherently suspect if scientific investigations document the quality of care given by non-physicians.[156] Nurse-midwives are one group for which such outcome

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[151]Tanney, *supra* note 45, at 1235.

[152]Joint Comm'n on Accreditation of Hosps., *supra* note 25, at 89.

[153]Hayman v. City of Galveston, 273 U.S. 414, 416-17 (1927); Don v. Okmulgee Memorial Hosp., 443 F.2d 234, 239 (10th Cir. 1971); Stern v. Tarrant County Hosp. Dist., 565 F. Supp. 1440, 1447 (N.D. Tex. 1983); *rev'd on other grounds*, 778 F.2d 1052 (5th Cir. 1985), *cert. denied*, 106 S. Ct. 1957 (1986); Aasum v. Good Samaritan Hosp., 395 F. Supp. 363, 371 (D. Ore. 1975), *aff'd*, 542 F.2d 792 (9th Cir. 1976); Levin v. Doctors Hosp., 233 F. Supp. 953, 955 (D.D.C. 1964), *rev'd per curiam on other grounds sub nom.* Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965); Settler v. Hopedale Medical Found., 80 Ill. App. 3d 1074, 1075-76, 400 N.E.2d 577, 578 (1980).

[154]*See* Gellhorn, *The Abuse of Occupational Licensing*, 44 U. Chi. L. Rev. 6, 6 & 25 (1976); Moore, *The Purpose of Licensing*, 4 J. Law & Econ. 93, 104 (1961). These articles argue that even licensing, although ostensibly to protect the public from incompetence, is too restrictive and results in protecting the licensees from competition.

[155]Fashion Originators' Guild of Am. v. Federal Trade Comm'n, 312 U.S. 457, 465 (1941); American Medical Ass'n v. United States, 130 F.2d 233, 245-49 (D.C. Cir. 1942), *aff'd*, 317 U.S. 519 (1943). *See generally* 1 P. Areeda & D. Turner, Antitrust Law ¶ 216b (1978).

[156]Dolan, *supra* note 150, at 686.

studies exist. These studies consistently show no difference in patient-outcomes or even better outcomes when childbirth care is provided by nurse-midwives as compared with physicians.[157] Thus, any exclusion of nurse-midwives as a group on the basis that they give lower quality care would be highly questionable.

B. Differences in the Effects of Due Process

Courts deciding privileges cases should also be sensitive to the differences in the operation of due process when a group of non-physicians has been excluded as opposed to an individual physician. Notice of the reason for denial and an opportunity to be heard can serve as effective safeguards for an individual physician against competitive abuses. A hearing and an internal appeal procedure provide an individual physician threatened with denial or termination of privileges an opportunity to show how his personal qualifications meet a presumably valid standard.[158] In contrast, when privileges are limited to physicians, a non-physician applicant, no matter how expert in his own field, is automatically barred. He is faced with trying to persuade the medical staff not only that he is highly qualified, but that the standard should be changed. Thus, a hearing and an appeal procedure may be of little help to the non-physician when the barrier is the standard itself.[159]

C. Examination of Procompetitive and Anticompetitive Effects

In applying the rule of reason to privilege denials and weighing the procompetitive and anticompetitive effects, courts must first recognize that there are three distinct markets involved: hospitals compete for patients, hospitals compete for providers, and providers compete for patients.[160] What is procompetitive in one market may be anticompetitive in another.[161]

Courts should also recognize that the structure of the market for in-patient hospital services creates a conflict of interest for physicians.

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[157]Levy, Wilkinson & Marine, *supra* note 50; Mann, *San Francisco General Hospital Nurse-Midwifery Practice: The First Thousand Births*, 140 AM. J. OBSTETRICS & GYNECOLOGY 676 (1981); Slome, Wetherbee, Daly, Christensen, Meglen & Thiede, *Effectiveness of Certified Nurse-Midwives*, 124 AM. J. OBSTETRICS & GYNECOLOGY 177 (1976).

[158]*See* Drexel, *The Antitrust Implications of the Denial of Hospital Staff Privileges*, 36 U. MIAMI L. REV. 207, 227 (1982).

[159]*See, e.g.*, Cooper v. Forsyth County Hosp. Auth., 604 F. Supp. 685, 687 (M.D.N.C. 1985), *aff'd*, 789 F.2d 278 (4th Cir. 1986) (granting staff privileges to plaintiff podiatrist would have required change in hospital by-laws); *cf.* Jost, *supra* note 24, at 907 (exclusion of a class of providers subject to criticism as denying procedural fairness).

[160]*See generally* Rafferty, *Comment*, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 207, 208 (1978).

[161]*See infra* notes 168-71 and accompanying text.

Although the hospital sells its services to patients, the physician acts as the patient's agent in the decision to purchase hospital services.[162] The physician decides whether the patient needs hospital care, what kind of care, and for how long. Aware that physicians thus control hospital utilization, hospitals compete for patients indirectly by competing for physicians.[163] Hospital decisions regarding what services to offer and who should offer them are aimed at making the hospital attractive to physicians.[164] On the other side of the hospital-patient transaction, physicians on the medical staff advise the hospital what services to offer. The power of physicians on both sides of this transaction creates a conflict of interest.[165] When a group of non-physicians is denied hospital privileges based on the advice of physicians on the medical staff, antitrust courts should be sensitive to this conflict of interest and scrutinize the extent to which the exclusion may serve the physicians' self-interest as well as or instead of the patient's interest.

1. Differences in Procompetitive Justifications for Privilege Denials.— One procompetitive justification for the denial of privileges to non-physicians that is no longer available to hospitals is that the denial is necessary to maintain the hospital's accreditation, which, in turn, is critical in qualifying for federal and private insurance payments.[166] The JCAH has recently changed its accreditation standards and no longer requires a hospital to restrict its staff to physicians and dentists to be accredited.[167]

From the perspective of the hospital-provider market, there is no price competition among hospitals for physicians because hospitals do not pay physicians. The main competitive variables here are quality and amenities; physicians want to be on staff at a hospital with a reputation for quality and at a hospital offering the services and equipment that facilitate the physician's work.[168] Thus, an exclusion that maintains or enhances a hospital's quality is procompetitive in the hospital-provider

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[162]Reinhardt, *Comment*, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 156, 157 (1978); Somers, *Comment*, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 469, 469-70 (1978).

[163]Redisch, *supra* note 79, at 231.

[164]Havighurst, *supra* note 31, at 1081; Salkever, *supra* note 113, at 197-98.

[165]E. FREIDSON, *supra* note 85, at 146-69; Havighurst, *supra* note 31, at 1104.

[166]Jost, *supra* note 24, at 843; *see also* Havighurst, *supra* note 31, at 1087-88. For cases in which accreditation is discussed in this manner, see, e.g., Wilk v. American Medical Ass'n, 719 F.2d 207, 214 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984); Williams v. Kleaveland, 1983-2 Trade Cas. (CCH) ¶ 65,486, 68,358 (W.D. Mich. 1983); Levin v. Doctors Hosp., 233 F. Supp. 953 (D.D.C. 1964), *rev'd per curiam on other grounds sub. nom.* Levin v. Joint Comm'n on Accreditation of Hosps., 354 F.2d 515 (D.C. Cir. 1965).

[167]*See supra* notes 34-36 and accompanying text.

[168]Salkever, *supra* note 113, at 198.

market.[169] In addition, a hospital's decision to deny staff privileges to non-physicians may be procompetitive in this market because the exclusion makes the hospital more attractive to physicians by insulating them from whole groups of competitors in the provider-consumer market for in-patient services.[170] The purpose of the antitrust laws, however, is to promote competition to benefit consumers.[171] A court faced with a privileges case should therefore focus on whether the denial is procompetitive from the consumer's viewpoint as well as from the physician's.

Other procompetitive justifications a hospital might assert for qualitatively screening individuals do not necessarily apply to the exclusion of entire groups of non-physicians. For example, because a hospital may be liable in tort for negligently screening or supervising members of its medical staff,[172] any exclusion that decreases the hospital's potential liability for malpractice is procompetitive in that it decreases the hospital's costs of doing business.[173] This rationale would justify excluding any individual who the hospital has reason to believe is likely to practice negligently, such as a physician with a history of several malpractice suits against him or a physician who attempts to practice beyond the scope of his expertise. This rationale would not justify excluding an entire group of non-physicians where there is no evidence that the group is prone to malpractice. For example, the rate of malpractice suits against nurse-midwives is one-tenth of the rate of suits against obstetricians.[174] The low rate for nurse-midwives is no doubt partially because nurse-midwives deliver primarily low-risk patients and because some nurse-midwives do no deliveries at all.[175] Nevertheless, a hospital should not

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[169]Enders, *supra* note 3, at 742.

[170]*Cf.* Kissam & Webber, *supra* note 66, at 610 (even with respect to fellow physicians, there is an incentive for physicians to want staff membership restricted to inefficient levels to increase excess capacity and physicians' own prestige and income).

[171]NCAA v. Board of Regents of the Univ. of Okla., 468 U.S. 85, 107 (1984); Marrese v. American Academy of Orthopaedic Surgeons, 706 F.2d 1488, 1495 (7th Cir. 1983), *rev'd on other grounds*, 105 S. Ct. 1327 (1985).

[172]Crumley v. Memorial Hosp., Inc., 509 F. Supp. 531 (E.D. Tenn. 1978), *aff'd mem.*, 647 F.2d 164 (6th Cir. 1981); Elam v. College Park Hosp., 132 Cal. App. 3d 332, 183 Cal. Rptr. 156 (1982); Joiner v. Mitchell County Hosp. Auth., 125 Ga. App. 1, 186 S.E.2d 307 (1971), *aff'd*, 229 Ga. 140, 189 S.E.2d 412 (1972); Darling v. Charleston Community Memorial Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966); Ferguson v. Gonyaw, 236 N.W.2d 543 (Mich. Ct. App. 1975); Johnson v. Misericordia Community Hosp., 99 Wis. 2d 708, 301 N.W.2d 156 (1981).

[173]Kaczanowski v. Medical Center Hosp. of Vt., 612 F. Supp. 688, 696 (D. Vt. 1985); Williams v. Kleaveland, 1983-2 Trade Cas. (CCH) ¶ 65,486, 68,358 (W.D. Mich. 1983); Drexel, *supra* note 158, at 231.

[174]*Malpractice Crisis Leaves Nurse-Midwives Without Coverage*, 4 PROF. REG. NEWS, July 1985, at 6.

[175]Levy, Wilkinson & Marine, *supra* note 50, at 51; Adams, *supra* note 50, at 1267. *But see id.* at 1270, noting increased involvement of nurse-midwives with complicated births.

be permitted to assert potential tort liability as a justification for excluding nurse-midwives.

This rationale may justify excluding chiropractors due to the hospital's potential liability for a chiropractor's misdiagnosis.[176] Orthodox health care providers do not agree with chiropractors that the cause of all disease is misalignment of the spine.[177] If, for example, a hospital x-ray for a chiropractor's patient revealed an operable tumor as the probable cause of the patient's symptoms, but the chiropractor proceeded to treat the patient by spinal manipulation, the hospital and its radiologist might be placed in a vulnerable position.[178]

Several state statutes as well as accreditation bodies require members of a medical staff to conduct peer review.[179] Staff members might be discouraged from participating in peer review or being candid in evaluating their colleagues if an expelled provider institutes an antitrust suit against the members of a review committee that recommended termination of privileges.[180] This potential chilling of peer review by antitrust litigation is a proper judicial concern and a valid procompetitive justification in privileges cases involving individuals.[181] Although this rationale might

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[176]Note, *supra* note 66, at 1194. Although there are no large scale studies of the quality of chiropractic care, there are assertions that chiropractic education is inadequate and that chiropractors tend to exceed the scope of their competence. *See generally* Ballantine, *Will the Delivery of Health Care Be Improved By the Use of Chiropractic Services*?, 286 NEW ENG. J. MED. 237 (1972); Firman & Goldstein, *The Future of Chiropractic: A Psychosocial View*, 293 NEW ENG. J. MED. 639 (1975); Silver, *Chiropractic: Professional Controversy and Public Policy*, 70 AM. J. PUB. HEALTH 348 (1980). There are also anecdotal reports of injuries caused by chiropractic treatment. *See, e.g.*, Braun, Pinto, DeFilipp, Lieberman, Pasternack & Zimmerman, *Brain Stem Infarction Due to Chiropractic Manipulation of the Cervical Spine*, 76 S. MED. J. 1507 (1983); Schmidley & Koch, *The Noncerebrovascular Complications of Chiropractic Manipulation*, 34 NEUROLOGY 684 (1984).

[177]Silver, *supra* note 176, at 348.

[178]*But cf.* Kissam & Webber, *supra* note 66, at 608-09 (suggesting hospital may not be liable for chiropractor's treatment error as long as hospital has exercised proper care in selecting chiropractor). Regarding the difficulty a hospital might have in screening chiropractors, see *infra* notes 188-89 and accompanying text.

[179]*See, e.g.*, IND. CODE § 16-10-1-6.5 (a) & (c) (Supp. 1985); ME. REV. STAT. ANN. tit. 24, § 2503 (1984-85); MICH. COMP. LAWS ANN. § 333.21513 (West Supp. 1985); 63 PA. CONS. STAT. ANN. § 425.1 (Purdon Supp. 1985); JOINT COMM'N ON ACCREDITATION OF HOSPS., *supra* note 21, at 107-09, 113.

[180]Where peer review is mandated by a state statute, staff members may have state action immunity to antitrust liability. Marrese v. Interqual, Inc., 748 F.2d 373 (7th Cir. 1984), *cert. denied*, 105 S. Ct. 3501 (1985); Lombardo v. Sisters of Mercy Health Corp., 1985-2 Trade Cas. (CCH) ¶ 66,749 (N.D. Ind. 1985). *But see* Jiricko v. Coffeyville Memorial Hosp. Medical Center, 628 F. Supp. 329, 333 (D. Kan. 1985) (no state action immunity where publicly-owned hospital did not provide due process to demoted physician); Quinn v. Kent Gen. Hosp., 617 F. Supp. 1226, 1236-40 (D. Del. 1985) (peer review not immune as state action because peer review statute does not reflect a legislative intent to displace competition with regulation).

[181]*See* Pontius v. Children's Hosp., 552 F. Supp. 1352, 1376 (W.D. Pa. 1982); Williams v. Kleaveland, 534 F. Supp. 912, 920 (W.D. Mich. 1981). Indeed, concern with this chilling

justify a deferential judicial approach where individual physicians lost hospital privileges as a result of peer review, the rationale does not support excluding an entire group of non-physician providers. If the group were granted privileges, evaluation by physicians or peers could still be done on an individual basis.

Another procompetitive effect of denying privileges to less qualified practitioners is that a hospital would incur high costs in monitoring these people if it could not initially qualitatively screen privileges applicants.[182] This rationale is another argument that does not, however, readily transfer from an individual to a group context because the rationale does not justify excluding an entire group unless there is some evidence that, in general, its members give inferior care.

If a specific non-physician group seeking privileges must have physician supervision of some aspects of its practice, the costs to the hospital of providing such supervision are a procompetitive justification for excluding the group.[183] Even the new, flexible JCAH standard restricts full medical staff membership to providers licensed to practice independently.[184] This justification would not apply, however, if the non-physician applicant has arranged for his own supervision by a doctor already on the staff. For example, although nurse-midwives legally require medical supervision for some types of services,[185] nurse-midwives challenging exclusion in *Nurse Midwifery Associates v. Hibbett*[186] had already arranged for the necessary supervision and did not ask the hospital to supply it.

Furthermore, even physicians require consultation with other physicians when they encounter an illness or clinical situation beyond their own fields of expertise. For example, a family physician may be required to call in an obstetrician when a maternity patient needs a caesarean section.[187] Although there is a distinction between medical supervision required by statute and consultation or back-up required by the hospital, hospitals and medical staffs have not found such cooperative arrangements unduly costly when only physicians were involved.

A hospital could assert, as a procompetitive justification for exclusion, that accommodating new types of staff members would create high

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effect largely prompted Congress to enact, in late 1986, a statutory provision for antitrust damages immunity for peer review of individual physicians. *See* Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, tit. IV; *see also supra* note 76.

[182]Drexel, *supra* note 158, at 232; Enders, *supra* note 3, at 743.

[183]*See* Kissam & Webber, *supra* note 97, at 655.

[184]Joint Comm'n on Accreditation of Hosps., *supra* note 21, at 101.

[185]*See supra* note 51 and accompanying text.

[186]549 F. Supp. 1185 (M.D. Tenn. 1982).

[187]*See* M. Roemer & J Friedman, *supra* note 22, at 284.

costs in developing standards and review mechanisms for the new group.[188] The key legal question, however, is whether these initial costs are outweighed by the benefit to the consumer of the increased competition from the new group. This argument might be a valid justification for excluding chiropractors because chiropractic is based on an entirely different theory of disease than orthodox medicine.[189] It is difficult to imagine how an institution, the hospital, based on a scientific-medical model of diagnosis and treatment could even begin to articulate standards for an alien ideology.

Consumers may have problems making informed choices in purchasing health or hospital care because information about the skill of a provider or the quality of a hospital is difficult for a lay person to obtain and evaluate.[190] Thus, in the hospital-patient market, the hospital's selectivity in staff membership is procompetitive because it reduces consumers' information search costs. The uninformed consumer can rely on the hospital's screening to provide at least some assurance that the hospital itself and the providers on its staff meet a professionally determined level of quality.[191] As applied to groups of non-physicians, however, the hospital's screening serves this function only if the group excluded in fact gives low quality care.[192] It is, therefore, reasonable to demand of a hospital that asserts this justification for excluding a group some qualitative evidence beyond the fact that the members of the group are not physicians.

Most of these procompetitive benefits are achievable by screening individuals and do not require excluding an entire group. Because the major factor on which hospitals compete with each other is quality, an antitrust ruling that decreases a hospital's ability to select among individuals on a quality basis would greatly diminish competition among hospitals. However, the consequences of prohibiting a hospital from

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[188]Kissam & Webber, *supra* note 66, at 655. Although not basing its decision on antitrust analysis, a New Jersey state court found that a hospital's inability to establish standards and supervise the care given by a new type of staff member was a reasonable basis for denying adjunct staff privileges to a certified psychiatric nursing specialist. Wrable v. Community Memorial Hosp., 205 N.J. Super. 438, 501 A.2d 187 (1985). Broad application of this court's reasoning could make it impossible for any new category of provider to obtain privileges.

[189]*See supra* note 177.

[190]Pauly, *Is Medical Care Different?*, in COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT, AND FUTURE 19, 28-34 (1978).

[191]*See* Quinn v. Kent Gen. Hosp., 617 F. Supp. 1226, 1239 (D. Del. 1985) (medical staff peer review "arguably procompetitive" by compensating for consumers' "relative lack of information about these matters"). *See generally* Jost, *supra* note 24, at 866-75 (while standards may thus reduce costs, they may also promote inefficiency if the standards are merely symbolic or force consumers to pay for something they don't need).

[192]Jost, *supra* note 24, at 906.

excluding an entire group without substantive evidence of a quality deficiency would not be as destructive of competition. The hospital could still be selective as to individuals within the group.

2. Differences in Anticompetitive Effects.—From the consumer's perspective, there are clear differences between excluding an individual and excluding a group in terms of anticompetitive effects. Denial of hospital privileges to an entire group of non-physicians has a much greater effect in foreclosing consumer choice than denial of privileges to an individual physician. According to the Seventh Circuit, "[A] consumer has no interest in the preservation of a fixed number of competitors greater than the number required to assure his being able to buy at the competitive price."[193] In the consumer-health care provider market, such factors as personalization of care, convenience, and variations in treatment modalities may be added to price as the salient competitive variables. Where the excluded individual offers essentially the same array of services at a similar price as other physicians in the geographic market, the loss of one physician has a minimal anticompetitive effect.[194] However, where the excluded individual offers a different, but still reasonably substitutable package of services, and the exclusion means that consumers will be unable to select that package at all, the anticompetitive effect is much greater. For example, in a market where six obstetricians and one nurse-midwife compete to sell health care to pregnant women, the loss of the midwife, who may have been offering more personalized care, greater flexibility in choices for delivery, and more health education,[195] forecloses consumer choice much more drastically than the loss of one of the obstetricians. In a recent antitrust case involving dentists, the Supreme Court emphasized that it does not look favorably upon agreements among competitors that limit consumer choice, "absent some countervailing procompetitive virtue."[196]

Also, the non-physicians who are barred from offering in-patient services generally charge less than the physicians with whom they compete. Podiatrists charge less than orthopedic surgeons,[197] psychologists charge

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[193]Marrese v. American Academy of Orthopaedic Surgeons, 706 F.2d 1488, 1497 (7th Cir. 1983), *rev'd on other grounds*, 105 S. Ct. 1327 (1985).

[194]*See* Williams v. Kleaveland, 534 F. Supp. 912, 920 (W.D. Mich. 1981); Hackett v. Metropolitan Gen. Hosp., 465 So. 2d 1246, 1257 (Fla. Dist. Ct. App. 1985). *See generally* R. POSNER, ANTITRUST LAW—AN ECONOMIC PERSPECTIVE 123 (1976) ("the elimination of an individual potential competitor can be expected to have no competitive significance at all"). *But see* Havighurst, *supra* note 31, at 1143 (elimination of a single physician may have anticompetitive ramifications justifying judicial oversight).

[195]*See* Comment, *supra* note 49, at 963 (describing physicians' childbirth services as technological and surgical in contrast with nurse-midwives' as natural and personalized).

[196]Federal Trade Comm'n v. Indiana Fed'n of Dentists, 106 S. Ct. 2009, 2018-19 (1986).

[197]AMERICAN PODIATRIC MEDICAL ASS'N, *supra* note 43, at 4 (podiatrists' charges are ten to fifty percent less than orthopedists').

less than psychiatrists,[198] nurse-midwives charge less than obstetricians,[199] and nurse-anesthetists charge less than physician anesthesiologists.[200] Therefore, denying privileges to allied health groups has the anticompetitive effect of maintaining higher prices in the provider-consumer market. The same is not true of the exclusion of an individual physician whose prices may be similar to those of other physicians in the market.

Another anticompetitive effect of excluding a group of non-physicians that does not apply to the exclusion of an individual physician is that restricting hospital privileges to physicians stifles innovation in health care delivery. From the consumer's perspective, where services offered by non-physicians are reasonably substitutable for services by physicians, the two groups compete.[201] However, where non-physicians also offer treatments not generally used by physicians, denying privileges to non-physicians retards the development of alternative approaches, even where such treatments have been proven safe and effective.[202] For example, nurse-midwives are inclined to use natural childbirth techniques rather than anesthesia,[203] and psychologists may offer biofeedback training rather than drugs as a treatment for chronic pain.[204] In addition to limiting consumers' options, barring these groups from hospital practice slows the acceptance of these safe and effective alternatives.

Finally, although excluding a single physician from hospital practice has a minimal anticompetitive effect in the provider-consumer market, excluding an entire group of non-physicians protects the dominant group (physicians) from all competition from an alternative group offering reasonably substitutable services at lower prices. Defending such an exclusion under the rule of reason on a quality basis is, in effect, an assertion that non-physicians should not be allowed to compete in hospitals. This assertion comes close to arguing that competition itself is unreasonable, an argument the Supreme Court flatly rejected in *National Society of Professional Engineers v. United States*.[205]

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[198]Tanney, *supra* note 45, at 1233.

[199]*See* Nurse Midwifery Assoc. v. Hibbett, 549 F. Supp. 1185, 1188 (M.D. Tenn. 1982) (excluded nurse-midwives alleged higher costs for maternity care in a market with only obstetricians).

[200]*FTC, Attorney General Come to Rescue of California CRNA*, 85 AM. J. NURSING 601, 601, 608 (1985).

[201]*See* Bhan v. NME Hosps., Inc., 772 F.2d 1467, 1471 (9th Cir. 1985); *FTC Addresses Key Question: Can Nurses and Doctors Compete?*, 4 PROF. REG. NEWS, Jan. 1985, at 2, 3.

[202]*See* Tanney, *supra* note 45, at 1235. *See generally* Ponsoldt, *supra* note 89, at 37-38 (analysis of how product standards created and enforced by dominant group of competitors result in eliminating competition from innovation).

[203]Comment, *supra* note 49, at 963.

[204]Tanney, *supra* note 45, at 1235.

[205]435 U.S. at 696; *see also* NCAA v. Board of Regents of the Univ. of Okla., 468 U.S. 85, 117 (1984) (rejecting rule of reason defense based on premise that competition itself is unreasonable).

VII. Suggested Judicial Approach

A relatively deferential judicial approach might be appropriate in privileges cases involving exclusions of individual physicians.[206] Physicians are better qualified than judges to evaluate other physicians. The content of the quality standard on which the exclusion is based, as the standard relates to training, experience, and expertise, is not suspect. Due process can effectively curb anticompetitive abuses. Most significantly for antitrust purposes, there is a minimal anticompetitive effect in any market.

However, because of the greater anticompetitive effect of precluding competition from an entire group, as well as other differences noted above, a quality of care standard invoked to exclude a group should be substantially related to the procompetitive justifications the hospital asserts.[207] A court should not merely defer to physicians' subjective opinions or allow a good faith defense. It is not unreasonable to demand some evidence that in general, the group excluded in fact provides inferior care.[208] Such a demand is consistent with the Supreme Court's recent decision in *Federal Trade Commission v. Indiana Federation of Dentists*.[209] "[E]ven if concern for the quality of patient care could under some circumstances serve as a justification for a restraint of [trade],"[210] defendants must produce sufficient evidence that the restraint in fact improves the quality of care. Mere expert opinion testimony may not be enough.[211]

A court should also require that the exclusionary standard be the least restrictive way to achieve the particular procompetitive benefit used to justify the standard. The least restrictive alternative concept appears in several antitrust cases involving industry self-regulation. Evaluating the antitrust liability of stock exchange self-regulation in *Silver v. New York Stock Exchange*,[212] the Supreme Court articulated "the principle that exchange self-regulation is . . . justified in response to antitrust charges *only to the extent necessary* to . . . [achieve] . . . the aims of the Securities Exchange Act[.]"[213] In a concurring opinion in *Professional*

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[206]*See* Havighurst, *supra* note 31, at 1133-35; Kissam & Webber, *supra* note 66, at 613, 638-39; *see also supra* notes 76 & 181.

[207]*Cf.* Kreuzer v. American Academy of Periodontology. 735 F.2d 1479, 1494 (D.C. Cir. 1984) (test for application of the rule of reason to exclusionary conduct by health professionals when a quality defense is asserted is whether there is a close rational nexus between the standard and quality of care).

[208]*See* Pontius v. Children's Hosp., 552 F. Supp. 1352, 1370-72 (W.D. Pa. 1982) (demanding substantial evidence to support exclusion of individual physician).

[209]106 S. Ct. 2009 (1986).

[210]*Id.* at 2021.

[211]*Id.* at 2020-21.

[212]373 U.S. 341 (1963).

[213]*Id.* at 361 (emphasis added).

Engineers,[214] Justice Blackmun found that even if one accepted a quality argument for the engineers' policy against competitive bidding, the "rule is still grossly overbroad."[215]

The Court of Appeals for the District of Columbia Circuit cited these aspects of *Silver* and *Professional Engineers* in a case involving the exclusion of an individual from a health professional association and held that "even if evidence existed in the record to support the asserted justification that the [limitation] improved the quality of patient care, *it must be shown that the means chosen to achieve that end are the least restrictive available.*"[216] Similarly, the Seventh Circuit, also citing *Silver* and *Professional Engineers*, has declared that where a patient care motive is used to justify exclusionary behavior by a health professional association, the defendant's conduct must meet a least restrictive alternative test.[217] Scholarly commentary also recommends a least restrictive alternative standard for potentially anticompetitive acts that result from industry self-regulation.[218]

As applied to individual practitioners, denial of hospital privileges is the least restrictive alternative for achieving various procompetitive benefits. When a hospital has reason to believe that an individual will provide low quality care because of deficient training, poor references, or a history of malpractice suits, forcing the hospital to nevertheless grant privileges, but closely monitor the individual's practice, would generate costs and potential liabilities for the hospital.

However, there are methods other than categorical exclusion of a non-physician group that can safeguard the quality of hospital care without limiting competition. A hospital could be selective as to individual non-physician applicants just as it is with physicians. Instead of barring all non-physicians, the hospital could provide for non-physicians' privileges, but admit only the most highly qualified podiatrists or psychologists, for example. With regard to standards of training, the appropriate focus is not on whether the training is less than that of physicians, because non-physician applicants are not seeking to practice medicine.

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[214]435 U.S. 679 (1978).

[215]*Id.* at 699 (Blackmun, J., concurring).

[216]Kreuzer v. American Academy of Periodontology, 735 F.2d 1479, 1491 (D.C. Cir. 1984) (emphasis added).

[217]Wilk v. American Medical Ass'n, 719 F.2d 207, 227 (7th Cir. 1983), *cert. denied*, 467 U.S. 1210 (1984).

[218]Ponsoldt, *supra* note 89, at 40-43, 59. A least restrictive alternative test is also recommended for scrutinizing exclusionary acts of joint ventures. Brodley, *Joint Ventures and Antitrust Policy*, 95 HARV. L. REV. 1521, 1536, 1568 (1982). A hospital and its medical staff may be characterized as a joint venture. *See* Kissam & Webber, *supra* note 66, at 656-59; *see also* Havighurst, *supra* note 31, at 1128-29 (recommending least restrictive alternative scrutiny of the hospital-medical staff joint venture, but focusing only on the structure, rather than the substance, of a privileges decision).

Rather, a court should consider whether the training is deficient in relation to what the applicant intends to do in the institution. For example, where podiatrists seek to perform more elaborate surgical procedures, a hospital could reasonably require advanced residency training or Board certification.[219]

Another less restrictive alternative is for a hospital to grant staff membership to non-physician groups, but limit specific clinical privileges, a practice analogous to the current policy of some hospitals which permit family physicians to deliver babies but require that an obstetrician perform caesarean births.[220] A court should be careful, however, that such limits are not so narrow as to be a sham. In *Davidson v. Youngstown Hospital Association*,[221] a podiatrist's privileges case brought on public policy grounds, podiatrists were permitted to cut toenails and trim callouses on a physician's order.[222] It is hard to believe that seven or eight years of professional education qualify podiatrists to do no more than cut toenails.[223] Finally, to avoid institutional costs of providing medical supervision for legally dependent providers, a hospital could require that an applicant needing physician back-up arrange for his own medical supervision by a staff member.[224]

VIII. Conclusion

Hospital privileges cases have presented courts with the thorny problem of protecting against anticompetitive abuses while guarding the legitimate interest of hospitals in maintaining high quality care.[225] A first step in resolving this problem is recognizing the clear differences between denial of staff privileges to an individual physician and denial to a group of non-physicians, differences in the substantive validity of the quality

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[219]Although podiatrists need only meet state licensure requirements in order to practice, podiatrists may obtain additional clinical training during a residency and demonstrate advanced knowledge by passing a Board examination. Of the 9,200 podiatrists in the United States, 2,400 are Board certified or Board eligible. American Podiatric Medical Ass'n, *supra* note 43, at 5. *But see* 50 Fed. Reg. 41,693, 41,695 (1985) (Federal Trade Commission charged that a hospital, in demanding that all podiatrists have a three-year residency without relating the residency requirement to specific surgical procedures, restrained competition in violation of the Federal Trade Commission Act).

[220]M. Roemer & J. Friedman, *supra* note 22, at 284.

[221]19 Ohio App. 2d 246, 250 N.E.2d 892 (1969).

[222]*Id.* at 252-54, 250 N.E.2d at 897.

[223]*See supra* note 37 and accompanying text.

[224]*Cf.* Reynolds v. Medical and Dental Staff of St. John's Riverside Hosp., 86 Misc. 2d 418, 382 N.Y.S.2d 618 (Westchester County Sup. Ct. 1976), *aff'd*, 55 A.D.2d 948, 391 N.Y.S.2d 382 (1977) (although hospital not obligated to directly employ a physician's assistant, it is obligated to provide appropriate privileges when assistant is employed by a physician staff member).

[225]Kissam & Webber, *supra* note 66, at 597.

rationale for exclusion, differences in the application of due process, differences in procompetitive justifications and differences in anticompetitive effects. A relatively deferential judicial approach to the exclusion of an individual physician might be appropriate. Because of these differences, however, when quality of care is invoked to justify excluding a non-physician group, judicial scrutiny should be based on a substantial relation and least restrictive alternative test. This approach would ensure that the rule of reason is not applied so deferentially as to insulate one powerful group of competitors from competition. In addition, this heightened scrutiny would uphold the fundamental principle that the purpose of the antitrust laws is to protect competition, not competitors.[226]

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[226]Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962).

Erratum: Volume 19 Issue 3 was incorrectly captioned Fall 1986. The correct date of Indiana Law Review Volume 19 Issue 3 is Summer 1986.

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