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# Notes and Comments

## Certificate of Need for Health Care Facilities: A Time for Re-examination

### I. Introduction

Faced with national health care costs that have soared from $28.98 per capita in 1940 to $141.63 in 1960, and then to $645.76 in 1976,[1] as well as with the inequitable distribution of health care resources,[2] Congress and the state legislatures have responded with a variety of mechanisms,[3] one of the most significant of which is Certificate of Need (CON) legislation.[4] The CON is a statement issued by a state agency containing the state's formal acknowledgement that a health care facility, medical equipment acquisition, or new program is "needed."[5] CON

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1. These health care expenditures represented 4.1% of the Gross National Product (GNP) in 1940, 5.2% of GNP in 1960, and 8.7% in 1976. D. ABERNETHY & D. PEARSON, REGULATING HOSPITAL COSTS: THE DEVELOPMENT OF PUBLIC POLICY 15 (1979).

2. The congressional findings incorporated into the National Health Planning and Resources Development Act of 1964 (NHPRDA) included the finding that "[t]he massive infusion of Federal funds into the existing health care system has contributed to inflationary increases in the cost of health care and failed to produce an adequate supply or distribution of health resources, and consequently has not made possible equal access for everyone to such resources." 42 U.S.C. § 300k(a)(2) (1982).

3. Among the approaches to solve the distribution problem is the Hill-Burton Act of 1946 under which the federal government provided funds for hospital construction pursuant to state health plans. Pub. L. No. 79-725, 60 Stat. 1040 (1946) (current version at 42 U.S.C. § 291 (1982)). In 1972, the Social Security Act was amended to include section 1122, which imposed capital expenditure review requirements on health care facilities receiving Medicare and Medicaid payments. Pub. L. No. 92-603, § 221(a), 86 Stat. 1329, 1386 (1972) (current version at 42 U.S.C. § 1320a-1 (1982)). For a description of section 1122, see J. SIMPSON & T. BOGUE, GUIDE TO HEALTH PLANNING LAW xvi-xvii (3d ed. 1985).

4. The NHPRDA called upon the states to "administer a State certificate of need program which applies to the obligation of capital expenditures within the State and the offering within the State of new institutional health services and the acquisition of major medical equipment and which is consistent with standards established by the Secretary by regulation." 42 U.S.C. § 300m-2(a)(4)(B) (1982).

5. Criteria for need are not limited to medical necessity. *See infra* text accompany-

statutes primarily affect institutional health care providers.[6]

The economic theory underlying CON programs is that government regulated centralization of specialized or expensive health care related services and equipment is necessary to produce the economies required[7] to halt the rapid escalation in health care costs. This theory, however, has not received universal acceptance among health care planners.[8]

Encouraged by a 1974 federal initiative in the form of the

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ing notes 56 and 57.

The CON is merely one of a number of requirements imposed on health care facilities. For example, individuals or organizations embarking on the establishment of a hospital must obtain a CON as a prerequisite to entering into any contractual relations involving capital expenditures for that hospital. Once these individuals or organizations, however, have constructed the hospital, they may not commence operating the hospital until an operating certificate has been obtained. N.Y. PUB. HEALTH LAW § 2805.1 (McKinney 1985). *See also id.* § 2805.2(b) providing that:

> An operating certificate shall not be issued by the department unless it finds that the premises, equipment, personnel, rules and by-laws, standards of medical care, and hospital service are fit and adequate and that the hospital will be operated in the manner required by this article and rules and regulations thereunder.

6. Although CON requirements initially applied only to acquisitions of major medical equipment by health care facilities, some states, following the lead of the federal government, have expanded their CON statutes so as to apply to acquisitions of major medical equipment by individual physicians. *See infra* notes 49-53, 81-86, and accompanying text.

Third party payors (health insurance carriers) generally do not pay facility fees where a CON has not been obtained. McNair, *Selected Issues in Forming and Operating Health Care Joint Ventures*, in HEALTH CARE, LEGAL RESPONSES TO NEW ECONOMIC FORCES 27 (R. McNair ed. 1985). The facility fee is a fee for the use of the physical premises on which health care is rendered. For example, a patient contemplating cataract surgery may find that his insurance company will pay the fee for use of a hospital's operating room, provided the hospital has obtained the required CON, but will not pay for use of an operating room in a physician's office or free-standing surgical center that lacks a CON.

7. For example, by limiting the number of beds in each hospital in a community to that for which there is a foreseeable use, government acts to eliminate the extra costs each hospital would otherwise incur for the maintenance of unoccupied beds. Limiting the number of hospitals can also produce savings. The administrative expenses involved in one 200-bed hospital would be less than the administrative expenses involved in two 100-bed hospitals. *See generally* Schonbrun, *Making Certificate of Need Work*, 57 N.C.L. Rev. 1259 (1979) (citing Roemer, *Bed Supply and Hospital Utilization*, HOSPITALS, Nov. 1, 1961).

8. For an evaluation of CON legislation, see OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, DEP'T OF HEALTH AND HUMAN SERVICES, REPORT TO CONGRESS, HOSPITAL CAPITAL EXPENSES: A MEDICARE PAYMENT STRATEGY FOR THE FUTURE 48-50 (1986) [hereinafter REPORT TO CONGRESS]. For a discussion of the efficacy of CON, see *infra* notes 202-17 and accompanying text.

National Health Planning and Resources Development Act (NHPRDA),[9] all states except Louisiana enacted CON legislation.[10] With President Reagan's signature on the Omnibus Health Package of 1986,[11] this federal initiative ended. The individual states must now meet the responsibility of re-examining their CON programs and making judgments as to whether these programs are valuable ones that should be continued wholly at state or local expense, with or without modification, or whether the critics of CON theory are correct, and their CON programs should be eliminated. This is the time to decide if CON programs are effective instruments in reversing the trend toward rapidly increasing health care costs and in ensuring that health care resources will be equitably distributed.

A re-examination must include an acknowledgement of the problems encountered by health care institutions and, perhaps more importantly, the attempts these institutions have made to circumvent the CON process. The reasons underlying the desire to circumvent could reveal the shortcomings of the CON process and point toward the necessity of developing other methods of cost containment and distribution of resources.

Part II of this Comment discusses the health care problems that CON was created to address. Part III surveys federal and state CON requirements. Part IV describes problems health care providers have faced in their attempts to comply with CON statutes, and mechanisms they have developed to circumvent the statutes. Part V analyzes these methods in light of the statutory framework of state CON statutes. Part VI considers the efficacy of the CON process.

This Comment concludes that consideration must be given to the replacement of CON legislation with other approaches to cost containment and equitable distribution of health care resources. It further concludes that in those states which choose to continue CON programs, the statutes must be unambiguous reflections of legislative intent in order to prevent the subversion

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9. 42 U.S.C. §§ 300k-300t-14 (1982). NHPRDA offered incentives to the states to enact CON legislation. *See infra* notes 26-61 and accompanying text.

10. *See infra* note 62 and accompanying text.

11. N.Y. Times, Nov. 19, 1986, at 1, col. 2 (reporting on the Act of Nov. 14, 1986, Pub. L. No. 99-660, tit. VII, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) ___).

of that intent by health care providers employing circumvention techniques, as well as by administrative agencies overstepping the boundaries of their authority.

## II. Underlying Problems Leading to the Enactment of CON Legislation

Soaring costs are but one aspect of the problems facing American health care.[12] The distribution of health care resources has been marked by regional and local variations that have left groups of individuals as well as whole communities bereft of necessary medical care.[13]

Since 1946, the federal government has evidenced legislative concern over the inability of the health care industry to provide facilities adequate to meet the health needs of all Americans.[14] In 1965, Congress created the Medicare[15] and Medicaid[16] programs to ensure that lack of funds would not cause the aged and needy to go without essential medical care. Medicare is funded through the federal government, while Medicaid involves joint funding by federal and state governments. Despite these efforts, medical services continued to be inaccessible to many Ameri-

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12. *See supra* note 1.

13. The congressional findings that were incorporated into the NHPRDA document the economic, sociologic, and medical problems related to health care. Pub. L. No. 93-641, § 2, 88 Stat. 2225, 2226 (1974) (codified at 42 U.S.C. § 300k (1982)). The national health care system suffers from "lack of uniformly effective methods of delivering health care." 42 U.S.C. § 300k(a)(3)(A) (1982). *See also infra* note 17 and accompanying text.

14. The Hill-Burton Act enacted in 1946 provided federal funds for hospitals constructed pursuant to state health plans. Pub. L. No. 79-725, 60 Stat. 1040 (1946) (current version at 42 U.S.C. § 291 (1982)). For a brief overview of this attempt to remedy regional hospital shortages, see McKray & McKray, *Federal Health Law in the United States*, in LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS 37-38 (R. Roemer & G. McKray, eds. 1980).

15. Pub. L. No. 89-97, tit. I, § 102, 79 Stat. 286, 291-332 (1965) (current version at 42 U.S.C. § 1395 (1982)). Medicare is a federal program of health insurance for the aged that is funded through the federal social security and railroad retirement systems. The basic medical coverage provided by Medicare can be augmented by voluntary participation in a supplementary insurance program, the premiums for which are paid jointly by the individual subscriber and the federal government. *See generally* 1986 MEDICARE & MEDICAID GUIDE (CCH) 5315-16.

16. Pub. L. No. 89-97, tit. I, § 121, 79 Stat. 286, 343-52 (1965) (current version at 42 U.S.C. § 1396 (1982)). Medicaid is a program of health insurance for certain economically disadvantaged persons that is funded jointly by federal and state governments. *See generally* 1986 MEDICARE & MEDICAID GUIDE (CCH) ¶ 14,010.

cans[17] and medical costs continued to rise.[18]

By 1974, Congress was convinced that the traditional marketplace forces were inadequate to create an appropriate health care system.[19] Patients, the health care consumers, do not ordinarily have the information or expertise necessary to make medical choices. Consequently, they rely heavily on their physicians' recommendations, or delegate decisions to their physicians entirely.[20] The physician makes the health care decision on the basis of technological feasibility and possible benefit to the patient, with little regard for the traditional factor of cost. The availability of insurance to provide payment of medical fees results in a disregard of cost by both patient and physician.[21] This places pressure on health care facilities to expand services and bed capacity and to acquire increasingly specialized equipment, even in the face of possible underutilization.[22] The cost of these underutilized services must be borne by the relatively few users, thus increasing the per use cost.[23] The premise behind CON is

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> Widespread access and distribution problems exist with respect to medical facilities and services. In many urban areas, hospitals, clinics and other medical care institutions and services are crowded into relatively tiny sectors, while large areas go poorly served or completely unserved. Many rural communities are completely without a physician or any other type of health care service, while adjacent urban areas are oversupplied.

S. REP. No. 93-1285, 93d Cong., 2d Sess. *reprinted in* 1974 U.S. CODE CONG. & ADMIN. NEWS 7879.

18. *See supra* note 1. *See also* 42 U.S.C. § 300k(a)(3)(C) (1982).

19. "The highly technical nature of medical services together with the growth of third party reimbursement mechanisms act to attenuate the usual forces influencing the behavior of consumers with respect to personal health services." S. REP. No. 93-1285, 93d Cong., 2d Sess. *reprinted in* 1974 U.S. CODE CONG. & ADMIN. NEWS 7878.

20. *Id.*

21. The insurance industry refers to this disregard of costs by an insured as the "moral hazard problem." The insured weighs the benefits of a treatment against his coinsurance payment rather than against the total cost of treatment, most of which is likely to be borne by the insurance company. P. JOSKOW, CONTROLLING HOSPITAL COSTS 21-31 (1981).

22. Blumstein & Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3, 5 (citing Salkever, *Competition Among Hospitals*, in FEDERAL TRADE COMM'N, BUREAU OF ECONOMICS, COMPETITION IN THE HEALTH CARE SECTOR: PAST, PRESENT AND FUTURE 191-206 (W. Greenberg ed. 1978)).

23. According to one study, an empty hospital bed will cost at least half the amount of an occupied one. Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83, 87 (citing INSTITUTE OF MEDICINE, NAT'L ACADEMY OF SCIENCES, CONTROLLING

that it can be a method of insulating health care facilities from the pressures to expand that are placed on them by physicians and patients.

Increased per use cost is but one way in which underutilization affects total medical expenditures. It has been argued that excess supply increases demand. The availability of health care services or facilities ensures their use — "a bed built" is "a bed filled."[24] This view, known as "Roemer's law," is an underlying assumption of CON legislation. By preventing underutilization through restriction on capital expansion, the growth in demand for medical resources can be curtailed.[25]

## III. National Health Planning and Resources Development Act

### A. *Federal Law*

Dissatisfaction with the meager success of previous attempts at health care planning led Congress to seek another approach to the problem.[26] In 1974, Congress added Title XV to

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THE SUPPLY OF HOSPITAL BEDS 7-16 (1976)).

24. Schonbrun, *supra* note 7, at 1263 (citing Roemer, *Bed Supply and Hospital Utilization*, HOSPITALS, Nov. 1, 1961, at 36).

The prospective payment scheme introduced into the Medicare system in 1983 discourages the use of equipment and services that are available, but not medically mandated, by providing the hospital with a preset payment that is determined by diagnosis and not by services rendered. *See infra* note 203.

25. *See generally* D. ABERNETHY & D. PEARSON, *supra* note 1, at 49-53 (discussing "Roemer's law" and supply-induced demand).

While "Roemer's law" is an underlying assumption of CON policy, several studies suggest that the theory is an invalid one. Blumstein & Sloan, *supra* note 22, at 25.

26. The Senate report accompanying S. 2994, which became Pub. L. No. 93-641, NHPRDA, stated that:

> Existing health planning activities . . . have been only marginally successful. The performance of individual areawide comprehensive health planning agencies has been spotty at best. Reasons for the failure of many health planning agencies to achieve a uniformly high level of performance . . . include an inadequately specific Congressional mandate at the time the legislation was originally enacted, inadequate funding, and inadequate authority to implement recommendations. In addition, the Department of Health, Education, and Welfare has, until recently, consistently failed to provide adequate resources, including technical assistance, to Comprehensive Health Planning Agencies to enable them to carry out their responsibilities satisfactorily. It is hoped by the Committee that the proposed legislation will go far toward solving these problems.

S. REP. No. 93-1285, 93d Cong., 2d Sess. *reprinted in* 1974 U.S. CODE CONG. & ADMIN.

the Public Health Service Act by enacting the National Health Planning and Resources Development Act[27] designed to create a nationwide health planning structure with the capability of developing and implementing policy.[28] Title XV of the Public Health Service Act:

1) established the National Council on Health Planning and Development[29] to advise the Secretary of Health and Human Services (HHS) (originally, Health, Education and Welfare) in issuing national guidelines for health care planning, a task made mandatory by the statute;[30]

2) established and provided funds for a nationwide system of health service areas, based on population and availability of resources, planning for which became the responsibility of Health Systems Agencies (HSA's)[31] designated by the Secretary of HHS after consultation with governors of the states in which

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27. Pub. L. No. 93-641, 88 Stat. 2225 (1974). This massive statute was codified at 42 U.S.C. §§ 300k-300t-14 (1982).

28. *See supra* note 26.

29. 42 U.S.C. § 300k-3 (1982). From its inception, NHPRDA provided for strong consumer representation on all agencies under its aegis. The original act required that there be a minimum of five persons who are not providers of medical care among the twelve voting members of the National Advisory Council. Pub. L. No. 93-641, § 1503(b)(1), 88 Stat. 2225, 2228 (1974). The Act was amended to increase the non-provider representation to eight of sixteen voting members. 42 U.S.C. § 300k-3(b)(1) (1982).

30. 42 U.S.C. § 300k-1 (1982).

31. An HSA was designated to serve as the local health planning agency for each health service area. A nonprofit corporation (but not an educational institution), a public regional planning body, or a single unit of local government was eligible for appointment by the Secretary of Health and Human Services. *Id.* § 300*l*-1(b)(1).

A majority of the HSA members, not to exceed 60%, had to be non-provider residents of the health service area and representative of the area's health care consumers. *Id.* § 300*l*-1(b)(3)(C)(i).

The purposes of the HSA were to: 1) improve the health of the area's residents; 2) increase the accessibility and quality of health services; 3) limit increases in costs of health services; 4) prevent unnecessary duplication of health services; and 5) improve competition in the health service area. *Id.* § 300*l*-2(a).

In furtherance of these purposes, HSA's were authorized to analyze data regarding need for, availability of, and utilization of health care resources in the health service area; develop, implement, and periodically review health systems plans for the health service area; approve or disapprove of the use of federal funds in the health service area; and review and make recommendations regarding institutional and home health services in the health service area. *Id.* § 300*l*-2(b). The HSA's were given the authority to create subarea councils, *id.* § 300*l*-1(c), and hire professional staffs, *id.* § 300*l*-1(b)(2).

the HSA's are located;[32]

3) provided assistance and funding to states for development of State Health Planning and Development Agencies (SHPDA's) that would, with the advice of the HSA's and Statewide Health Coordinating Council (SHCC), formulate state health plans, and be responsible for the administration of Certificate of Need programs;[33] and

4) required the states, as a prerequisite to receiving federal funds for health planning, to enact and administer CON statutes.[34]

The legislative history of NHPRDA, as well as its language, indicates that the heart of the statute was the CON requirement.[35] Congress viewed the state CON programs as an indispensable part of its program to eliminate unnecessary capital expenditures that had resulted in the rapid increase in the cost of health care.[36] It was a must for states to "administer a State certificate of need program which applie[d] to the obligation of capital expenditures within the State and the offering within the State of new institutional health services and the acquisition of major medical equipment."[37] The failure of a state to put such a program into effect within a specified period of time would have resulted in the inability of the Secretary of Health and Human Services to "make or enter into any such allotment, grant, loan, loan guarantee, or contract"[38] authorized by the Act. Since 1982, however, funding has been drastically reduced, and there have been no sanctions for noncompliance. The noncompliance issue has been mooted by the abrogation of Title XV of the Public Health Service Act.

Although, through NHPRDA, the federal government mandated CON programs, this mandate was addressed to the states and not to the health care facilities. It was the individual state,

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32. *Id.* § 300*l*-4(b).

33. *Id.* §§ 300m-300m-6. *See supra* notes 4-6, 8-10.

34. 42 U.S.C. §§ 300m(d)(2)(D), 300m-2(a)(4)(B) (1982).

35. *Id.*

36. Pub. L. No. 93-641 "recognized State certificate-of-need programs to be the basic component in an overall effort to control the unneccessary capital expenditures which contribute so greatly to the total national health bill." S. REP. No. 96-96, 96th Cong., 1st Sess. 5, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS 1310.

37. 42 U.S.C. § 300m-2(a)(4)(B) (1982).

38. *Id.* § 300m(2)(D).

through its police power, that would enact the CON statute and regulations with which health care facilities were required to comply.[39] The federal law, however, has had great bearing on the interpretation of the state laws because NHPRDA and its accompanying amendments and regulations have provided a model to which the states have looked in writing and in interpreting their statutes and regulations.[40]

NHPRDA required the SHPDA to provide for CON review prior to implementation of:[41]

1) acquisition of major medical equipment costing in excess of $400,000;[42]

2) other obligations of capital expenditures in excess of

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39. In a set of challenges to the constitutionality of federal and state CON requirements, North Carolina's states'-rights argument was rejected and the federal requirement was held not to infringe upon that state's rights even though enactment of a CON statute would violate North Carolina's constitution. In *In re* Certificate of Need for Aston Park, 282 N.C. 542, 193 S.E.2d 729 (1973), North Carolina's highest state court ruled the state's CON law was an impermissible exercise of the state's police power and was violative of the state's constitution because there was no rational relationship between the state's legitimate interest in public health and the denial of a nonprofit hospital corporation's right to construct on private land, and with private funds, an adequately staffed and equipped hospital. North Carolina had refused to grant a CON to the hospital corporation because the state determined that an adequate supply of hospital beds already existed in the area. While the decision to build may well be an economically unsound one on the hospital's part, the court reasoned, it is not within the authority of North Carolina's legislature, as prescribed by the state's constitution, to protect the hospital from bad business judgment, nor is it within the authority of the state legislature to protect existing hospitals from competition. *Id.* at 551-52, 193 S.E.2d at 735-36.

The combination of the North Carolina court's prohibition against a state CON statute and the NHPRDA requirement of a CON statute as a funding prerequisite led North Carolina to challenge the constitutionality of NHPRDA. In North Carolina *ex rel* Morrow v. Califano, 445 F. Supp. 532 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978), the district court held that NHPRDA was not an unconstitutional violation of states' rights because a state is free to decline to enact CON legislation even though this would mean that the state would not receive funds under NHPRDA. The court additionally found NHPRDA to be rationally related to the legitimate interest that the federal government has in the national health, and as such, is permitted to contain conditions ensuring that federal funds will be efficiently used to further the national health. *Id.* at 535.

40. For a comprehensive listing of the cases interpreting federal and state CON laws, see J. SIMPSON & T. BOGUE, *supra* note 3.

41. Excluded from CON review are activities that are solely for research. 42 C.F.R. § 123.404(d) (1985).

42. Pub. L. No. 97-35, § 936(a)(3), 95 Stat. 357, 572 (1981) (codified at 42 U.S.C. § 300n(7) (1982)) amending Pub. L. No. 96-79, § 117(b)(3), 93 Stat. 592, 619 (1979) (setting the major medical equipment monetary threshold at $150,000).

$600,000, indexed for inflation;[43]

3) capital expenditures resulting in a substantial change in bed capacity;[44]

4) capital expenditures resulting in a substantial change in health services provided by a health care facility;[45] and

5) offer of a new health service or reinstatement of a discontinued health service.[46]

Institutional health care providers, such as hospitals or nursing homes, were subject to CON review. Federal regulations defined "health care facilities" as hospitals, skilled nursing facilities, kidney disease treatment centers, intermediate care facilities, rehabilitation facilities, and ambulatory facilities.[47] Health maintenance organizations (HMO's) were largely exempt from CON review.[48]

NHPRDA's focus on institutional health care providers created a loophole that permitted private physicians to purchase equipment for their offices without CON review, while hospitals could purchase the same equipment only after going through CON review. The concern developed that this loophole was re-

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43. Pub. L. No. 97-35, § 936(a)(2), 95 Stat. 357, 572 (1981) (codified at 42 U.S.C. § 300n(6) (1982)) amending Pub. L. No. 96-79, § 117(b)(3), 93 Stat. 592, 619 (1979) (setting the capital expenditure monetary threshold at $150,000). The cost of studies, plans, and other activities preliminary to the aquisition must be included in determining whether the $400,000 and $600,000 thresholds have been reached. 42 U.S.C. § 300n(6) and (7) (1982).

44. 42 U.S.C. § 300n(6)(B)(ii)(II) (1982).

45. *Id.* § 300n(6)(B)(ii)(III).

46. 42 C.F.R. § 123.404(a)(3) (1985).

47. *Id.* § 123.401.

48. 42 U.S.C. § 300m-6(b) (1982). Among the national health priorities set by NHPRDA was the development of HMO's, and thus, they were placed outside the reach of this statute: "The Congress finds that the following deserve priority consideration: . . . development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care." *Id.* § 300k-2(a).

By exempting HMO's from CON, a major barrier to their market entry was removed. This special status was conferred on HMO's because of the expectation that they would provide health care more efficiently than would the traditional fee-for-service system. HMO's differ from the fee-for-service system by providing health care at a prepaid per capita fee. The HMO assumes the responsibility for delivering a specified range of health care services to the enrollees, who pay a set periodic fee that is independent of their use of the health care services. *See generally* H. LUFT, HEALTH MAINTENANCE ORGANIZATIONS: DIMENSIONS OF PERFORMANCE (1981).

sulting in a decentralization and duplication of services that should have been centralized for optimal use of health care services, as well as for cost containment.[49]

In response to this concern, an amendment to NHPRDA was proposed that would have extended CON coverage to the acquisition of all expensive major medical equipment, whether by institutional health care providers or by private physicians.[50] While this proposal received the support of such institutional health care providers as the American Hospital Association,[51] organized physicians opposed the extension, in any form, of CON review to physicians' offices.[52] The amendment that was ultimately passed represented a compromise between these two positions. A middle ground between requiring a CON for all physi-

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49. The Senate Report urging passage of the 1979 amendment to the NHPRDA expanding CON coverage to acquisitions by noninstitutional providers stated: "Such exemption of noninstitutional providers has already led to a vast and perhaps unnecessary proliferation of high-cost technology such as CAT (computerized axial tomography) scanners, with enormous potential for improper or overutilization and a consequent increase in costs throughout the health system." S. REP. No. 96-96, 96th Cong., 1st Sess. 8, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS 1306, 1313.

50. *See id.* at 73-74, *reprinted in* 1979 U.S. CODE CONG. & ADMIN. NEWS at 1378-79 (discussing the difference between the original proposal and the amendment that was enacted).

51. "We believe that the private offices of health practitioners should be subject to CON review to the extent that those offices are proposing to obtain highly specialized equipment or develop facilities that are typically provided in an institutional setting." *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. 587 (1978) (statement of John Alexander McMahon, Pres., American Hosp. Ass'n).

52. The American Medical Association's statement in opposition to the extension of the CON requirement pointed to the negative effects this extension would have on both health care availability and health care costs.

> We must also consider the possible long range effects of extending certificate of need to the physicians' office. For example, restricting the physician's use of medical technology could impede the development and refinement of new medical discoveries. Such an extension could also lead to an increase in health care costs. It is well established that many procedures can be performed in the physician's office less expensively than in a hospital. Applying certificate of need to physicians' practices could restrict the performance of many of these procedures to institutional settings, thus increasing costs.
>
> We are also concerned that this could lead to the establishment of "franchises" in medicine that will restrict the availability of medical services to patients and restrict the entry of new health professionals into the system. This would adversely affect rural and shortage areas.

*Id.* at 614 (prepared statement submitted by the American Medical Ass'n).

cians making capital expenditures for major medical equipment, and requiring a CON for no physicians, was chosen. The resulting provision broadened NHPRDA's scope to include noninstitutional health care providers, such as individual physicians or groups of physicians, to the extent that they acquired expensive equipment located *outside* of a hospital but used to service inpatients of a hospital.[53]

Another provision of the 1979 amendment brought within the scope of CON acquisitions made "on behalf of a health care facility" as well as acquisitions made "by" the health care facility itself.[54] Legislative history provides little insight into the meaning of "on behalf of a health care facility." Administrative agencies have interpreted the phrase in a variety of ways, and the results of the small amount of litigation prompted by the phrase show no clear trend.[55]

CON review is a multi-layered procedure. The HSA's and SHPSA's adopt review procedures and criteria to govern the administration of the CON program. The federal legislation required that the criteria be in accord with those set forth in NHPRDA and its accompanying regulations.

The major factors that states were required to consider when formulating their criteria included: (1) the relationship between the proposal and the health system plan; (2) the relationship between the proposal and the long term plan of the provider making the proposal; (3) less costly or more effective alternatives; (4) the financial feasibility of the proposal and its effect on the provider's costs and charges; (5) the need that the serviced population has for the proposed service, and the extent to which the population, especially its disadvantaged members, will have access to the services; (6) the extent to which the proposal will meet the health needs of the traditionally medically

53. The amendment was phrased in terms of an exemption. It required all physicians acquiring major medical equipment to file notice of such acquisition with the designated state agency. Only those acquisitions that would "be used to provide services for inpatients of a hospital" and those acquisitions for which the state agency learned that no notice was filed would be subject to CON review. All other acquisitions of major medical equipment by physicians would be exempt from review. Pub. L. No. 96-79, § 117(a), 93 Stat. 592, 618 (1979) (codified at 42 U.S.C. § 300m-6(e) (1982)).

54. Pub. L. No. 96-79, § 117(b)(3), 93 Stat. 592, 619 (1979) (codified at 42 U.S.C. § 300n(6) (1982)).

55. *See infra* note 112 and accompanying text and text accompanying notes 159-73.

underserved; (7) the availability of resources required to provide the proposed service; (8) the effect of the proposal on the clinical needs of health professional training programs; (9) the relationship of the proposal to energy conservation; (10) the effect of the proposal on competition for using and providing health care; (11) the efficiency of existing services similar to those proposed; and (12) the quality of care offered by the proposed provider in the past.[56]

These criteria went far beyond a determination of actual need, and relied heavily on an economic assessment of the proposal. Resulting decisions may, therefore, have varied considerably from decisions arrived at from a purely medical perspective.[57]

The NHPRDA provided that after a health care facility submitted a completed application for a project, the first level of review would be conducted by the HSA.[58] This itself might be multi-layered, with hearings conducted by subarea advisory councils, HSA review committees, executive committees, or subcommittees.[59] The HSA would send its findings and recommendations to the SHPSA, which was required to give consideration to the HSA's report, but the SHPSA would be ultimately responsible for the CON decision.[60] Furthermore, a provision for administrative and judicial review was required.[61]

### B. *State Laws*

Although NHPRDA stimulated state enactment of CON laws, a number of states had some form of CON requirement

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56. 42 C.F.R. § 123.412 (1985).

57. For an analysis of the factors determining "need", see Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSRO's*, 1975 Nw. U.L. Rev. 6, 27.

58. 42 C.F.R. § 122.304 (1985). There may be a requirement for the filing of a letter of intent preceding a formal application. *See, e.g.*, Alaska Admin. Code tit. 7, § 07.030 (Oct. 1980).

59. For a comprehensive outline of the steps involved in CON review, see Barton, *Health Planning Regulation of Hospitals*, in Representing Health Care Facilities 86-99 (M. Strickler & F. Ballard, Jr., eds. 1981).

60. 42 U.S.C. § 300m-6(a)(2), (g) (1982).

61. *Id.* § 300n-1(b)(12). Administrative agency decisions were required to be upheld by reviewing courts unless they were "found to be arbitrary or capricious or not made in compliance with applicable law." *Id.* § 300n-1(b)(12)(E).

prior to NHPRDA.[62] NHPRDA provided only minimal requirements, and states were not precluded from imposing more stringent regulations.[63] State CON statutes vary in the extent to which they satisfied the minimal federal requirements.[64]

When Congress increased the monetary amount above which major medical equipment and other capital expenditures became subject to CON review,[65] not all states responded with similar increases. Consequently, there are wide variations in monetary thresholds among the states.[66] Additionally, there are variations in the coverage of certain services irrespective of threshold.[67]

Among the states with monetary thresholds below the federal requirement[68] is New York. In addition to a $300,000

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62. In 1964, New York became the first state to enact a CON statute. Maryland and Rhode Island followed in 1968; California and Connecticut in 1969; Arizona, Massachusetts, Minnesota, Nevada, New Jersey, North Dakota, Oklahoma, Oregon, South Carolina, and Washington in 1971; Florida, Kansas, Kentucky, Michigan, and South Dakota in 1972; and Colorado, Tennessee, and Virginia in 1973. CHAYET & SONNENREICH, P.C., CERTIFICATE OF NEED: AN EXPANDING REGULATION CONCEPT 5-6 (1978).

Louisiana never enacted a CON statute. Letter from Bonnie W. Smith, Louisiana Bureau of Health Planning, to author (Sept. 15, 1986).

Montana's CON statute is scheduled to expire on July 1, 1987. 1983 MONT. LAWS 329 § 13.

The following states either repealed or allowed their CON statutes to expire: Arizona in 1985, Letter from Doris Evans-Gates, Arizona Dep't of Health Services to author (Oct. 15, 1986); Idaho in 1983, Letter from Rose Bowman, Idaho Dep't of Health and Welfare to author (Sept. 19, 1986); Kansas in 1985, Letter from Ron Henricks, Kansas Office of Health and Environmental Planning to author (Sept. 12, 1986); Minnesota in 1984, Letter from Sr. Mary Madonna Ashton, Minnesota Dep't of Health to author (Sept. 12, 1986); New Mexico in 1983, Letter from Thomas D. Regas, New Mexico Health and Environment Dep't to author (Sept. 16, 1986); Texas in 1985, Letter from Robert Bernstein, Texas Dep't of Health to author (Sept. 26, 1986); and Utah in 1984, Letter from Blaine A. Goff, Utah Dep't of Health to author (Sept. 15, 1986).

63. For example, while the federal law did not require a CON for medical equipment costing less than $400,000, New York requires that hospitals acquiring medical equipment costing $300,000 or more must obtain a CON. Thus, more projects would come within the scope of CON under the New York monetary threshold than under the federal monetary threshold. *See infra* note 68 and accompanying text and text accompanying note 69.

64. For states that failed to satisfy the minimal federal requirements with respect to monetary thresholds see *infra* note 75. *See also supra* text accompanying notes 37-38 (denying federal funds to states in cases of noncompliance).

65. *See supra* notes 42-43 and accompanying text.

66. *See infra* notes 68, 72, 75, and accompanying text.

67. *See infra* text accompanying notes 70-71, 73-74.

68. By requiring a CON for major medical equipment costing less than the $400,000

threshold,[69] New York requires CON review for the following activities regardless of cost when they are done by health care facilities: conversion or addition of beds; therapeutic radiology; open heart surgery; cardiac catheterization; kidney, heart, liver and bone marrow transplants; chronic renal dialysis; computer axial tomography (CAT) scanners; burns care; extracorporeal shockwave lithotripters; and acquired immune deficiency syndrome (AIDS) centers.[70] Review is also required for any proposal which, although less than $300,000, is part of a project exceeding a total cost of $3,000,000.[71]

Among the states with thresholds equal to the federal requirement[72] is New Jersey. Additionally, New Jersey requires

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federal threshold, the following states impose a greater obstacle to expansion of health care than did the federal statute: Alabama (major medical equipment, $253,085), Memorandum, Michael O. Emfinger, Director, Alabama State Health Planning Agency (Aug. 29, 1986); Hawaii (new major medical equipment, $250,000), HAW. REV. STAT. § 323D-2 (1985); Maine (major medical equipment, $300,000; capital expenditures, $350,000), ME. REV. STAT. ANN. tit. 22, §§ 303(12-A), 304-A(3) (Supp. 1986); Rhode Island (for any expenditure resulting in a change in bed capacity or services, $300,000 until June 30, 1987, $450,000 until June 30, 1988 at which time it will rise to $600,000), R.I. GEN. LAWS § 23-15-2(10)(B) (Supp. 1985); Vermont (major medical equipment, $250,000), VT. STAT. ANN. tit. 18, § 2403(a)(3) (Supp. 1986); (capital expenditures, $300,000), VT. STAT. ANN. tit. 18, § 2403(a)(2) (Supp. 1986).

69. N.Y. COMP. CODES R. & REGS. tit. 10D, § 710.1(c)(1)(vi) (1986).

70. *Id.* § 710.1(c)(2)(i)(a), (b).

71. *Id.* § 710.1(c)(2)(i)(c). This total project threshold makes it more difficult in some circumstances to circumvent the CON process through piecemeal acquisition. *See infra* notes 106-08 and accompanying text.

72. These states, some of which index the threshold for inflation, are: Alabama (non-major medical equipment), Memorandum from Michael O. Emfinger, Alabama State Health Planning Agency (Aug. 29, 1986); Connecticut, CONN. GEN. STAT. ANN. § 19a-155(a) (West 1986); District of Columbia, D.C. CODE ANN. § 32-302(3)(A)(iv) and (11)(a)(b) (Supp. 1986); Georgia, GA. CODE ANN. § 31-6-2(14)(B) and (F) (1985); Hawaii (replacement of major medical equipment and other capital expenditures including new major medical equipment), HAW. REV. STAT. § 323D-2 (1985); Kentucky, KY. REV. STAT. ANN. § 216B.015(6) (16) (Michie/Bobbs-Merrill 1982); Maryland (capital expenditures other than those for major medical equipment), MD. HEALTH-GEN. CODE ANN. § 19-115(j)(i)(1)-(4) (Supp. 1986); Massachusetts, MASS. REGS. CODE tit. 105, § 100.020 (1986); Missouri, MO. ANN. STAT. 197.305(6) (Vernon Supp. 1987); Nebraska (major medical equipment), NEB. REV. STAT. § 71-5831 (Supp. 1984); Nevada, NEV. REV. STAT. § 439A.100-2 (1985); New Hampshire (major medical equipment), N.H. REV. STAT. ANN. § 151-C:2 XXIV (Supp. 1986); New Jersey, N.J. ADMIN. CODE tit. 8, § 33-1.4(a)1, 2 (Supp. 1985); South Carolina, S.C. Dep't of Health and Envtl. Control Reg. No. 61-15 § 103(13) (Apr. 1980); South Dakota, S.D.CODIFIED LAWS ANN. § 34-7A-23(17), (26) (1986); Virginia, VA. CODE ANN. §§ 32.1-102.1 (1985); West Virginia, W. VA. CODE § 16-2D-2(i), (t) (Supp. 1986); and Wyoming, WY. DEP'T OF HEALTH AND SOCIAL SERVICES, RULES AND REGULA-

CON review for the following activities of health care facilities, regardless of cost: initiation of new health care services; regionalized services; bed additions, reductions, or conversions; changes in a facility that will cause access problems to its traditionally served population; transfer of a hospital patient care service from one corporate entity to another; and transfer of ownership.[73] Any acquisition in a twelve month period of a group of similar equipment units or system parts where each unit or part is individually below the threshold, but has a cumulative total of over $400,000, requires CON review.[74]

A growing number of states increased their thresholds significantly above the federal requirement.[75] Oklahoma's threshold for initial acquisition of major medical equipment is the highest in the nation — $3,000,000.[76] Replacement of major medical equipment already in use at a health care facility is exempt from review.[77] The threshold for other capital expenditures has been programmed to escalate from $3,000,000 for fiscal year 1987 to $5,000,000 for fiscal year 1989.[78]

All states with CON statutes subject institutional health care providers to CON review.[79] Most states, New Jersey and New York being notable exceptions, require CON review for

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TIONS GOVERNING CERTIFICATE OF NEED, CH. III, § 2 (1985).

73. N.J. ADMIN. CODE tit. 8, § 33-1.4 (Supp. 1985).

74. *Id.* § 33-2.7(a)2.

75. These states are: Alaska ($1,000,000 threshold), ALASKA STAT. § 18.07.031 (1986); California ($1,000,000), CAL. HEALTH AND SAFETY CODE § 437.10(d), (e)(3)(A) (West Supp. 1987); Colorado ($1,000,000, major medical equipment; $2,000,000, other capital expenditures), COLO. REV. STAT. § 25-3-503(6.5)(a), (1.5)(a) (Supp. 1984); Indiana ($1,000,000), IND. CODE ANN. § 16-1-3.7 (Burns Supp. 1986); North Carolina ($600,000, major medical equipment; $1,000,000, capital expenditures other than those for major medical equipment), N.C. GEN. STAT. § 131E-176(15), (16)b (1986); Oregon ($1,000,000, major medical equipment), OR. REV. STAT. § 442.025(25) (1985); Washington ($1,000,000), WASH. REV. CODE § 70.38.025(2), (5), (12) (West Supp. 1986); and Wisconsin ($1,000,000), Dep't of Health and Social Services, Annual Adjustment of Ch. 150, Wis. Stats., Dollar Threshold, eff. Jan. 1, 1986.

76. 1986 Okla. Sess. Law Serv. ch. 149 § 5 (West) (to be codified at OKLA. STAT. tit. 63, § 2651.2(2)(g)).

77. OKLAHOMA HEALTH PLANNING COMM'N, PROCEDURES FOR PROJECT REVIEW UNDER THE STATE CERTIFICATE OF NEED LAWS 3 (May 29, 1986).

78. 1986 Okla. Sess. Law Serv. ch. 149 § 5 (West) (to be codified at OKLA. STAT. tit. 63, § 2651.2(2)(e)).

79. An exclusion for HMO's is typical. *See, e.g.*, MASS. GEN. LAWS ANN. ch. 111, § 25C½ (West 1983). *See also supra* note 48 and accompanying text (discussing federal exemption for HMO's).

capital expenditures incurred *by or on behalf of* a health care facility.[80] The extent to which coverage extends to private physicians acquiring major medical equipment, however, creates significant differences among the states.

A number of states require all private physicians to obtain a CON when acquiring major medical equipment in excess of the threshold.[81] Other states have incorporated into their statutes a variation of the 1979 federal amendment[82] that extends CON coverage to physicians who acquire major medical equipment that will be used to treat inpatients of a hospital.[83] A third

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80. " 'Reviewable activity' means . . . [t]he obligation by or on behalf of a health care facility of a capital expenditure . . . ." OHIO REV. CODE ANN. § 3702.51(R)(1) (Page Supp. 1985). This conforms to the 1979 federal amendment. *See supra* text accompanying notes 54-55.

81. *See, e.g.* HAW. REV. STAT. § 323D-54 (1985):

> Nothing in this part or rules thereunder with respect to requirement for certificates of need applies to . . . [o]ffices of physicians, dentists, or other practitioners of the healing arts in private practice as distinguished from organized ambulatory health care facilities, *except in any case of purchase or acquisition of equipment attendant to the delivery of health care service and the instruction or supervision therefor for any private office or clinic involving a total expenditure in excess of the expenditure minimum.*

*Id.* (emphasis added).

For similar provisions, see NEV. REV. STAT. § 439A.015 (1985); OR. REV. STAT. §§ 442.320(1), 442.340(7) (1985); R.I. GEN. LAWS §§ 23-15-2(11), 23-15-4 (1985); S.D. CODIFIED LAWS § 34-7A-23(26) (1986); W. VA. CODE § 16-2D-4(a) (Supp. 1986); WIS. STAT. ANN. § 150.61(3) (West Supp. 1986).

82. *See supra* notes 49-53 and accompanying text.

83. *See, e.g.* MASS. GEN. LAWS ANN. ch. 111 § 25C (West 1983):

> No person . . . shall acquire for location in other than a health care facility a unit of medical, diagnostic, or therapeutic equipment with a fair market value in excess of one hundred and fifty thousand dollars unless the person . . . notifies the department of the person's . . . intent to acquire such equipment and of the use that will be made of the equipment. . . . A determination by the department of need therefor shall be acquired for any such acquisition . . . if the department finds . . . that the equipment will be used to provide services for inpatients of a hospital other than on an occasional and irregular basis.

*Id.*

For similar provisions, see ME. REV. STAT. ANN. tit. 22, § 304-A(2) (West Supp. 1986); NEB. REV. STAT. § 71-5831 (Supp. 1984); N.C. GEN. STAT. §§ 131E-176(16)(h), 131E-178(c) (1986); WASH. REV. CODE ANN. § 70.38.105(4)(f)(ii) (Supp. 1987).

Maine is considering expanding its coverage to include the acquisition of certain equipment, such as Magnetic Resonance Imaging (MRI), by physicians even when not for regular use for hospital inpatients. Letter from Trish Riley, Maine Bureau of Medical Services, to author (Oct. 27, 1986).

MRI is a non-invasive diagnostic imaging technique that subsitutes radiowaves and magnetic fields for the ionizing radiation employed by CAT scanners and ordinary x-

group has specific statutory exclusions for private physicians.[84] Another group makes little or no provision for private physician CON coverage. New York's statute addresses only "construction of a hospital,"[85] and is silent regarding private physicians. Connecticut is silent with respect to private physicians except for the acquisition of imaging equipment.[86]

## IV. The Institutional Health Care Provider in the CON Maze

### A. *Burdens Encountered in Complying with Requirements*

Once a health care facility decides to make an application for a Certificate of Need, there are many potential sources of delay. The actual application can take months to prepare and, regardless of how lengthy it is, additional information is frequently requested.[87] For example, the CON application filed by a group of Connecticut hospitals for a magnetic resonance imaging (MRI) center was over 1400 pages, and the required supple-

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rays. It provides pictures that differentiate among types of tissue and does so without interference from bone. Because of the ability of the technique to detect subtle physical and chemical differences, it offers the possibility of early detection of disease. E. STEINBERG & A. COHEN, NUCLEAR MAGNETIC RESONANCE IMAGING TECHNOLOGY: A CLINICAL, INDUSTRIAL & POLICY ANALYSIS 3 (1984).

84. "No health care facility shall be constructed or expanded, and no new health care services shall be instituted after the effective date of this act except upon application for and receipt of a certificate of need as provided by this act." N.J. STAT. ANN. § 26:2H-7 (West Supp. 1986); " 'Health care service' . . . exclud[es] services provided by a physician in his private practice. . . ." *Id.* § 26:2H-2b. For similar provisions, see ALA. CODE § 22-21-260(5) (1984); ALASKA STAT. § 18.07.111(9) (1986); DEL. CODE ANN. tit. 16, § 9302(4) (1983 & Supp. 1986); GA. CODE ANN. § 31-6-47(a)(4) (1985); KY. REV. STAT. § 216B.020(2)(a) (Michie/Bobbs-Merrill 1982 & Supp. 1986).

85. The New York statute defines "construction" broadly to include "erection, building, or substantial acquisition, alteration, reconstruction, improvement, extension or modification of a hospital, including its equipment; the inspection and supervision thereof; and the studies, surveys, designs, plans, working drawings, specifications, procedures and other actions necessary thereto." N.Y. PUB. HEALTH LAW § 2801(5) (McKinney 1985).

86. The Connecticut statute provides:

> [A]ny person proposing a capital expenditure to acquire imaging equipment having a cost exceeding four hundred thousand dollars, including the leasing of such equipment, which imaging equipment will not be owned by or located in a health care facility or institution . . . shall submit a request for approval of any such imaging equipment.

CONN. GEN. STAT. ANN. § 19a-155(b) (West 1986).

87. Interview by the author with Edward M. Kenney, President, Greenwich Hospital Association, in Greenwich, Conn. (June 30, 1986).

ment exceeded 1700 pages.[88] From conception until final approval, Greenwich Hospital's noncontroversial and unopposed request for a CON to replace its telephone system took one year, and that period was "brief" only because the hospital agreed to waive its right to a hearing.[89]

Review of an application may also be delayed by "batching," which requires applications for similar facilities or services to be evaluated contemporaneously and measured against each other. Many states follow the federal model for batching.[90] Further delays may be caused by declarations of moratoria on review of CON applications.[91]

The cost of applying for a CON can be considerable, exceeding $100,000 for major projects.[92] If litigation is required, the cost may reach $350,000.[93]

There is considerable bargaining involved in CON applications.[94] The HSA may indicate that it will approve the request only if the hospital agrees to decertify a specific number of beds.[95] In situations where hospitals do not actually possess, nor

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88. *Id.*

89. *Id.*

90. The federal model makes "provision for all completed applications pertaining to similar types of services, facilities, or equipment affecting the same health service area to be considered in relation to each other." 42 U.S.C. § 300n-1(b)(13)(A)(iii) (1982).

91. A moratorium on certain types of hospital expenditures is among the methods attempted by some states to make their CON statutes more effective. REPORT TO CONGRESS, *supra* note 8, at 48.

92. Interview with Edward M. Kenney, *supra* note 87.

93. Pantalena, *Certificate of Need*, 6 WHITTIER L. REV. 845, 845-46 (1984). One analyst claims that the high cost of litigation is no deterrent to health care facilities because the cost can be passed along to third party payors. Price, *Health Systems Agencies and Peer Review: Experiments In Regulating the Delivery of Health Care*, in LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS 373 (R. Roemer and G. McKray eds. 1980). This may be precluded by the greater scrutiny of health care costs now engaged in by third party payors. Whether third party payors accept this pass-along or not, the fact remains that dollars are being diverted from direct patient care.

94. Interview with Edward M. Kenney, *supra* note 87.

95. Wisconsin has a program of "bed banking" which allows hospitals to deactivate beds without permanently relinquishing the certification for these beds. A hospital may be required to "bed bank" as a result of its application for approval for a non-bed related capital expenditure. WISCONSIN DEP'T OF HEALTH AND SOCIAL SERVICES, BED BANKING: WISCONSIN CAPITAL EXPENDITURE REVIEW PROGRAM (undated). Reactivation of the 'banked" beds must be preceded by notice to the Division of Health and must be based on increased patient use of the hospital facilities. WIS. ADMIN. CODE § HSS 123.30(4), (5) (1985).

have a present need for the maximum number of permitted beds, they are reluctant to decertify because, if future circumstances require additional beds, they will be compelled to go through CON review to reinstate the beds.[96] Hospitals want the flexibility created by a reserve of unused beds. If a hospital is operating at 80% capacity, the remaining 20% idle capacity is not truly unproductive. It is a "safety margin," to prevent delays or denials of admission which can lead to death, pain, and greater curative costs.[97]

### *A Case Study*

Even where a state agency works along with the hospital, the process of filing a CON application can be burdensome and unreasonable in the hospital's view. A case in point is the CAT (Computerized Axial Tomography)[98] scanner at White Plains

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96. Interview with Edward M. Kenney, *supra* note 87.

97. Phillip, Mullner, & Andes, *Toward A Better Understanding of Hospital Occupancy Rates*, in HEALTH CARE FINANCING REV. 53, 54 (1984).

In a protest against the Hudson Valley Health Systems Agency's proposal to decrease the number of hospital beds within the HSA's area, Dr. Sanford Kaplan, Chairman, Legislation Committee, Westchester Medical Society, stated:

> The Westchester County Medical Society is certainly not opposed to reducing the number of unneeded hospital beds. But what constitutes a lack of need? Certainly it is not a matter that can simply be extended from occupancy rates (on an annualized basis). Illness, and consequently hospital occupancy, has seasonal variation. A bed empty in the summer during vacation periods may be desperately needed in the winter.
>
> Shall we risk the nonavailability of a bed in dead winter for a patient with an acute myocardial infarction (heart attack) and sacrifice medicine's enhanced capacity to salvage life from the throes of death with such patients? One need only go to the Emergency Rooms of White Plains, Lawrence, St. John's and Northern Westchester Hospitals — where nightly patients are held in those emergency rooms for extended hours because of the unavailability of hospital beds — to understand the complexities of the problems.

Kaplan, *Reducing Number of Hospital Beds is 'Politics' and Overlooks Public Need*, N.Y. Times, Feb. 6, 1987, § 11 (Westchester), at 32, col. 1.

98. The CAT (also referred to as the CT, computerized transaxial tomography) scanner is a diagnostic technique that "permits the visualization of structures which are not noted or poorly noted on traditional x-rays. Its major advantages are its sensitivity and safety compared to traditional x-rays and other alternatives to x-rays." Draft Memorandum of N.Y. Dep't of Health, Feb. 24, 1986 (accompanying proposal to amend CON statute). *See infra* text accompanying notes 193-97 (discussing the bill to amend New York's CON statute to extend coverage to acquisitions of CAT scanners by noninstitutional health care providers as well as by institutional health care providers).

Hospital Medical Center (WPHMC), White Plains, New York.[99] The experience is described here, not because it is an interesting anomaly, but rather, because it is typical in terms of both the hospital's actions and the CON process.

In 1976, a number of hospitals in Westchester County, New York, filed CON applications for CAT scanners. CON's were issued to New Rochelle Hospital Medical Center and to the Westchester County Medical Center, with a view toward regional use of both scanners. The hospitals that were denied the CON's, WPHMC among them, encouraged their radiologists to obtain and operate their own CAT scanners. WPHMC's radiologist opened an office in the basement of the medical office building located next to the hospital, installed a CAT scanner in the office, and used it to meet the hospital's CAT scanner needs.

While technically fulfilling the hospital's requirements and making available what has come to be considered a significant modality for diagnosing head or spinal trauma, the arrangement was not without health risks. It meant transporting an injured patient outside of the hospital and into an uncontrolled environment, and frequently required sending five or six staff members along with the patient. In January 1980, the hospital's administrators met in Albany with the Director of the Office of Health Systems Management (OHSM) to develop a solution to this unsafe and costly problem. The Director of OHSM was sympathetic to the hospital's concerns and instructed the hospital administration to file a CON application to lease space in the hospital proper to its radiologist who, in turn, would supply the CAT scanner and service. The application was filed, went through several levels of review, and was finally rejected by the Hudson Valley Health Systems Agency (HVHSA). On appeal, the rejection was affirmed.

The hospital's administrators returned to the Director of OHSM, who told them to file again, this time stating that the hospital would be responsible for billing and quality assurance. When the CON was still not forthcoming, OHSM advised WPHMC to send OHSM a letter agreeing to have the radiologist

99. Information regarding the White Plains Hospital CAT scanner was obtained in an interview by the author with Jon Schandler, President, White Plains Hospital Medical Center in White Plains, N.Y. (June 25, 1986).

own the CAT scanner, but lease it to the hospital, which would operate the scanner. Finally the CON was issued and the HVHSA chose not to appeal.

This resulted in the placement of a CAT scanner in the hospital. Although the hospital was permitted to lease and operate the scanner, and bill its patients for the scanner's use, the hospital was not permitted to own the scanner; the radiologist filled this role. In October of 1982, the hospital applied for a CON to own and operate the CAT scanner it housed. The CON was granted in May 1986, forty-three months after this last application, and ten years after the original application was filed.

When the hospital made its initial application, it projected the use of a CAT scanner at 1,200 scans a year. In the first year of operation, the scanner use was 2,500 scans. As of June 1986, its annual use was up to 6,000,[100] and was the most highly utilized General Electric CAT scanner in the northeast.[101]

### B. *Circumventing the Requirements*

The burdens imposed by CON review have prompted health care facilities to seek ways of avoiding the requirement.[102] Among the approaches they have taken are: piecemeal acquisition of major equipment where the components are below the monetary threshold for CON review;[103] use of parent corporations and their subsidiaries to provide benefits to health care facilities;[104] and arrangements between health care facilities and private physicians whereby the private physicians obtain major

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100. How much of the increased use is due to "Roemer's law," to the practice of defensive medicine in the wake of physicians' increasing fears of malpractice suits, or to more extensive understanding of the technology, needs to be investigated. *See supra* text accompanying notes 24-25 (explaining Roemer's law).

101. To achieve the economies that centralization can produce, HSA's in New York have set minimum uses for CAT scanners. If it does not appear that a proposed CAT scanner will be called upon to provide the annual minimum number of procedures, the CON for the CAT scanner will be denied. In 1982, HVHSA lowered its CAT scanner minimum to 1,800 procedures a year. HUDSON VALLEY HEALTH SYSTEMS AGENCY, MEDICAL FACILITIES PLAN 11 (1983).

102. Health care regulators are not insensitive to the problems involved in the CON process. Minutes of meetings of the Maine CON Work Group (Apr. 16, 1986, May 21, 1986 and Oct. 7, 1986) reveal concerns about improving the process.

103. *See infra* notes 106-09 and accompanying text.

104. *See infra* notes 110-12 and accompanying text.

medical equipment, the benefits of which are made available to the health care facility.[105]

### 1. *Piecemeal Acquisition*

The first of the circumvention devices, piecemeal acquisition, is illegal in most instances.[106] A recent attempt in Maryland to categorize a two-story addition to a hospital as two separate projects failed.[107] Attempts have been made in Illinois to avoid CON review by breaking projects down into smaller units. Some of these attempts have been successful despite the state's use of funding sources as a method for linking these smaller units. Funding source linkage involves the examination of uses to which projects having a common source of funds are put.[108] Review of projects to determine whether they are functionally interdependent has been another means employed by Illinois to deter circumvention of the CON process through piecemeal acquisition.[109]

### 2. *Corporate Structure*

There is a paucity of cases involving the use of parent corporations to avoid review.[110] This method, however, is not uncommon, and is openly employed.[111] In a typical situation, a hospital seeks to construct a parking garage for the convenience of

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105. *See infra* text accompanying notes 113-54.

106. *See, e.g.*, KY. REV. STAT. ANN. § 216B.061(2) (Michie/Bobbs-Merrill 1982): "No person shall separate portions of a single project into components in order to evade any expenditure minimum set forth in this chapter. For purposes of this chapter, the acquisition of one (1) or more items of functionally related diagnostic or therapeutic equipment shall be considered as one (1) project."

107. Southern Maryland Hospital constructed a two-story addition and contended that each floor was a separate project below the monetary threshold and thus not subject to CON regulations. The Maryland Health Resources Planning Commission and the hospital entered into a consent agreement whereby the hospital would be permitted to use only one floor of the addition until it received a CON, and the hospital would donate $25,000 to a charity. Wash. Post, Feb. 19, 1986, at C3, col. 3.

108. Letter from Bernard J. Turnock, Director of Public Health of the State of Illinois to author (Oct. 31, 1986).

109. *Id.*

110. Inquiries made by the author to the health departments of each state have yielded no reported cases involving CON circumvention in this manner, and only a small number of unreported cases.

111. Interview with Edward M. Kenney, *supra* note 87.

its patients and staff. Because the hospital is a health care facility, and because the garage may involve a capital expenditure in excess of the threshold, the hospital must apply for a CON. To avoid this, the hospital creates a parent corporate entity with two subsidiary corporations, one of which is the hospital. The second subsidiary is not a health care provider and, arguably, not subject to the CON statute. It builds and operates the garage with the result that the hospital has the parking facilities it requires, without subjecting the project to CON review.[112]

### 3. *Arrangements Between Health Care Facilities and Private Physicians*

The third device, arrangements between health care facilities and private physicians, has been possible in states that failed to extend their CON statutes to physicians' offices in accordance with the federal amendment.[113] Challenges to such arrangements have occurred in New York and New Jersey.[114] The CON statutes of these two states do not include a counterpart to the federal amendment that required a CON for acquisitions by physicians of major medical equipment that would service hospital inpatients or for acquisitions made *on behalf of a health care facility.*[115]

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112. At least one attempt to circumvent CON in this manner failed because the project was determined to be "on behalf of a health care facility." An injunction was granted, halting the construction of a four and a half million dollar garage on the grounds of a District of Columbia hospital. The court held that the builder of the garage, the corporate parent of the hospital, was acting on behalf of the hospital and was therefore required to obtain a CON prior to constructing the garage. District of Columbia v. Washington Hosp. Center Health Sys., No. 6970-83 (D.C. Super. Ct. Jul. 25, 1983).

113. *See supra* note 53.

114. *See infra* text accompanying notes 116-54 (discussing Finger Lakes Health Sys. Agency v. St. Joseph's Hosp., 81 A.D.2d 403, 442 N.Y.S.2d 219 (3d Dep't 1981), *aff'g* No. 2520/79 (Sup. Ct. Chemung County June 20, 1980); Clifton Springs Sanitarium Co. v. Axelrod, 115 A.D.2d 949, 497 N.Y.S.2d 525 (4th Dep't 1985); and Radiological Soc'y of N.J. v. N.J. State Dep't of Health, Hosp. Rate Setting Comm'n, 208 N.J. Super. 548, 506 A.2d 755 (1986)).

115. *See infra* notes 50-55, 80-86, and accompanying text.

a. Finger Lakes Health Systems Agency v. St. Joseph's Hospital

One New York challenge was decided in *Finger Lakes Health Systems Agency v. St. Joseph's Hospital.*[116] St. Joseph's was a private hospital in Chemung County in New York that owned the Elmira Medical Arts Center, an office building located thirty-five feet from its hospital building.[117] Although the two buildings were connected by a covered walkway, the Medical Arts Center was a separate entity from the hospital and did not have the tax exempt status enjoyed by the hospital.[118] The Medical Arts Center's tenants were private physicians who treated patients on an outpatient basis.[119]

In 1978, before there was a CAT scanner in Chemung County, the Finger Lakes Health Systems Agency (FLHSA) advised the hospitals in the area that it was developing plans for a CAT scanner and anticipated designating only one scanner for the county.[120] Upon learning this, and in disregard of FLHSA's request that hospitals take no action until its plans were formulated,[121] St. Joseph's constructed an addition to the Medical Arts Center.[122] The hospital leased the addition to a doctor who installed in it a CAT scanner that he had leased from a third party who had acquired it with private funds.[123] No CON was applied for or received.[124]

In its action against St. Joseph's for violation of New York's CON statute, FLHSA argued that St. Joseph's was the real owner and operator of the CAT scanner and had acquired it in violation of the law.[125] Although the hearing officer stated in his findings that he was unable to determine if St. Joseph's was offering the CAT scan service, he did conclude that the hospital

116. 81 A.D.2d 403, 442 N.Y.S.2d 219 (3d Dep't 1981), *aff'g* No. 2520/79 (Sup. Ct. Chemung County June 20, 1980).

117. Finger Lakes Health Sys. Agency v. St. Joseph's Hosp., No. 2520/79, slip op. at 5 (Sup. Ct. Chemung County June 20, 1980).

118. *Id.*

119. *Id.*

120. *Id.* at 6.

121. *Id.*

122. *Id.*

123. *Id.* at 7.

124. *Id.* at 10.

125. *Id.* at 9-10.

was giving the public the impression that it was offering the service.[126]

The trial court concluded that the arrangement may well have been devised to avoid CON review, but that there was nothing in it that violated the letter of the law.[127] The hospital did not need a CON to construct an addition to its office building because the office building was not a hospital or part of a hospital, not constructed under the hospital building code, and did not have the hospital's tax exempt status.[128] The rent that the leasing doctor paid to the hospital was rationally related to the construction costs.[129] The court found it irrelevant that the motive may have been to avoid the law. The law itself had not been violated.[130] Of particular significance to the court in reaching this conclusion was the absence of any exclusive access to the CAT scanner on the part of the hospital's physicians.[131]

The Appellate Division neither accepted nor rejected the trial court's reasoning, but upheld its decision because the CAT scanner arrangement was a *fait accompli*, and it found no useful purpose to be served by reversing the decision.[132] The Court of Appeals declined to review this holding.[133]

b. Clifton Springs Sanitarium Co. v. Axelrod

A recent challenge[134] to a similar scheme was also resolved in favor of a hospital. In this case, however, the reviewing court reached the issues. Using private funds, Clifton Springs Sanitarium purchased a trailer which it installed on its grounds eight feet from its hospital building.[135] A walkway and electrical lines connected the trailer to the hospital building.[136] The trailer was leased to a staff radiologist who leased, and later purchased, a

126. *Id.* at 8.
127. *Id.* at 26.
128. *Id.* at 27.
129. *Id.* at 27-28.
130. *Id.* at 29.
131. *Id.* at 28.
132. 81 A.D.2d at 408-09, 442 N.Y.S.2d at 223 (3d Dep't 1981).
133. 55 N.Y.2d 606, 449 N.Y.S.2d 1025 (1982).
134. Clifton Springs Sanitarium Co. v. Axelrod, 115 A.D.2d 949, 497 N.Y.S.2d 525 (4th Dep't 1985).
135. *Id.*, 497 N.Y.S.2d at 526.
136. *Id.*

CAT scanner.[137] The radiologist performed CAT scans on inpatients of Clifton Springs Sanitarium, inpatients of other hospitals, and outpatients in the area.[138] No CON was obtained.[139]

New York State brought an action against the hospital for operating a CAT scanner without a CON.[140] The Administrative Law Judge[141] concluded that the hospital had violated the law, and the state then ordered the doctor to discontinue performing CAT scans on patients of Clifton Springs Sanitarium.[142] The Appellate Division annulled the determination, holding that a CON was not required because the CAT scan services were provided by a private physician and not by the hospital.[143] The court took note that the trailer was purchased with private money and was not part of the hospital or constructed according to the hospital building code;[144] that the scanner was the property of the doctor;[145] that the doctor was not required to perform scans on the hospital's patients;[146] and that the radiologist paid the staff and billed the patients directly.[147] Here, again, the Court of Appeals declined to review the decision.[148]

c. Radiological Society of New Jersey v. New Jersey State Department of Health, Hospital Rate Setting Commission

Conversely, a New Jersey court, deciding *Radiological Society of New Jersey v. New Jersey State Department of Health, Hospital Rate Setting Commission*,[149] read that state's CON statute as being applicable to private physicians who provide services to inpatients of a hospital.[150] Despite the New Jersey

137. *Id.*
138. *Id.*
139. *Id.*
140. *Id.*
141. In conformity with the federal requirement, New York makes judicial review available following agency adjudication. *See supra* note 61 and accompanying text.
142. 115 A.D.2d at 949, 497 N.Y.S.2d at 526.
143. *Id.* at 949-50, 497 N.Y.S.2d at 527.
144. *Id.* at 950, 497 N.Y.S.2d at 527.
145. *Id.*
146. *Id.*
147. *Id.*
148. 67 N.Y.2d 609 (1986).
149. 208 N.J. Super. 548, 506 A.2d 755 (1986).
150. *Id.* at 561, 506 A.2d at 762.

statute's private physician exclusion,[151] the *Radiological* court held that a physician who acquires a CAT scanner and magnetic resonance imaging (MRI) equipment must first obtain a CON. In so holding, the court relied on a regulation[152] adopted by the New Jersey Department of Health in response to the 1979 federal amendment extending CON coverage to physicians in such situations.[153] The court relied additionally on a New Jersey Department of Health regulation giving the department the right to deny reimbursement for services provided to hospital inpatients where state or federal CON regulations are violated.[154] It would thus appear that, had the court found that the state health regulation subjecting the physicians in this case to CON review was not authorized by the state statute, it would nevertheless have denied the physicians' reimbursement because they failed to comply with federal CON regulations.

## V. Analysis

The potential for institutional health care providers to expand their services or make capital acquisitions without CON review depends on the degree to which the state statute conforms to federal requirements with respect to thresholds and to providers covered.

The states with high thresholds for review[155] stimulate less interest in circumventing CON review because it is easier for a health care facility to stay within the limits.[156] States with lower thresholds spawn efforts on the part of health care facilities and

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151. *See supra* note 84 (excluding physicians from CON review).

152.

> Acquisition of major movable equipment not owned by or located in a hospital requires a Certificate of Need *if the acquisition is made by or on behalf of a central services facility or will result in the creation of a central services facility and the equipment will be used to provide services to inpatients of one or more hospitals and the acquisition results in a capital expenditure greater than $150,000 per unit.*

208 N.J. Super. at 554, 506 A.2d at 757-58 (citing N.J. ADMIN. CODE tit. 8, § 33-1.5(d)(3)) (emphasis in original).

153. *Id.*, 506 A.2d at 757.

154. *Id.* at 555, 506 A.2d at 758 (citing N.J. ADMIN. CODE tit. 8, § 31B-4.32(d)).

155. *See supra* note 75.

156. "The usual way of avoiding review is to develop projects which do not exceed the expenditure minimums." Letter from Michael E. Henry, Missouri Dep't of Health, to author (Oct. 10, 1986).

physicians to circumvent the literal requirements of CON legislation. Separating projects into individual below-threshold units is one such attempt.[157] In most circumstances, however, such "separation" is illegal by statute.[158]

The use of creative corporate structuring devices to avoid review depends upon whether the state statute includes a CON requirement for acquisitions *on behalf of* a health care facility[159] and, where it does have this requirement, how the phrase *on behalf of* is interpreted. For example, a Washington, D.C., court read this language to include the benefit to a hospital of a parking garage developed by a subsidiary of the hospital's corporate parent.[160] Illinois takes the position that any project that "will serve hospital inpatients, places the hospital at financial risk or is governed by the hospital administration"[161] is deemed to be *on behalf of* the hospital, and therefore subject to review.[162]

A Nebraska court, on the other hand, has interpreted *on behalf of* more narrowly, holding that a separate tax entity that constructs a physicians' office building adjacent to a hospital is not subject to CON, because *on behalf of* does not necessarily mean *for the benefit of*.[163] The Nebraska case involved two entities. The first was the Lincoln Hospital Association (LHA), a not-for-profit corporation formed to build, endow, and maintain Lincoln General Hospital (LGH), which it transferred to the City of Lincoln.[164] LHA was a separate tax entity from LGH. It invested and supervised assets donated to it.[165] LGH was the

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157. *See supra* notes 106-08 and accompanying text.

158. There are several ways in which states prevent separation into components for the purpose of avoiding CON review. Maine requires that the cost of studies, plans, and other preacquisition activities be included in the cost of a project. ME. REV. STAT. ANN. tit. 22, § 303 (12-A) (West Supp. 1986). New Jersey requires a CON review for the acquisition of a group of similar units of equipment the total cost of which exceeds $400,000 in a 12 month period. N.J. ADMIN. CODE tit. 8, § 33-2.7(a)(2) (Supp. 1985). *See also supra* note 106.

159. *See supra* note 80.

160. *See supra* note 112.

161. Letter from Bernard J. Turnock, Director of Public Health of the State of Illinois, to author (Oct. 31, 1986).

162. *Id.*

163. State v. Coleman, No. 354-194 (Lancaster County Dist. Ct. Sept. 24, 1982).

164. Plaintiff's Petition for Injunction at 2, *Coleman* (No. 354-194).

165. *Coleman*, No. 354-194, slip op. at 2.

second entity. Prior to 1979, there had been an "alter ego"[166] relationship between LHA and LGH. In 1979, the Lincoln City Council required that the two entities maintain separate legal identities and that they not have interlocking board memberships.[167]

The controversy arose when LHA entered into a contract for the construction of an addition to a medical office building that it had leased from LGH and that was on LGH property.[168] The state, arguing for CON review, contended that the recitation of benefits to the hospital in the lease — e.g., the physical proximity of the offices of its medical staff to the hospital building — was evidence of an expenditure *on behalf of* the hospital.[169]

LHA maintained that this was not the sort of activity that the statute covered. LHA embarked on the project after making a careful determination that the project would be profitable.[170] If a corporation without LHA's historical relationship with LGH were to construct a medical office building adjacent to LGH, there would indeed be a benefit to LGH, but no one would argue that the resulting building was *on behalf of* the hospital. It should be no different in this situation.[171] LHA's reasoning prevailed and, accordingly, the court decided in its favor.[172] The state did not appeal.[173]

It would thus seem that, if there is an interest being served other than the hospital's, the fact that the hospital's interest is being served as well, will not cause that activity to be characterized as one that is *on behalf of* the hospital. But, if the hospital is the *sole* beneficiary, the project would probably be considered *on behalf of* the hospital.

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166. The "alter ego" doctrine involves a blurring of the distinction between two entities whereby a corporate entity may be merely a conduit for the transaction of a stockholder's private business. BLACK'S LAW DICTIONARY 71 (5th ed. 1979).

167. Letter from Douglas L. Curry, Esq. to Marilyn B. Hutchinson, Ass't Att'y Gen'l (June 16, 1981).

168. Defendant's Answer at 1, *Coleman* (No. 354-194).

169. Plaintiff's Petition for Injunction at 3, *Coleman* (No. 354-194).

170. Letter from Douglas L. Curry, Esq. to Dave Calhoun, Chairman, Lincoln Hospital Association (Aug. 13, 1981).

171. *Id.*

172. *Coleman*, No. 354-194, slip op. at 2.

173. Letter from Douglas L. Curry, Esq. to author (Oct. 24, 1986).

Unfortunately, the legislative history of the 1979 amendment adding the *on behalf of* language to the federal law offers no clear indication of the meaning of the term. Because the phrase was part of the same comprehensive amendment that included the elimination of the physician loophole,[174] it may be inferred that Congress intended the *on behalf of* language to widen the range of reviewable entities. This reasoning, however, can hardly be transferred to those states that have adopted the *on behalf of* language, but have failed to adopt provisions subjecting physicians to CON review.

Where statutes specifically cover private physicians, whether in all their major medical acquisitions or only in their acquisitions that will regularly be used to service hospital patients,[175] the wide extent of the law is clear. These states followed the lead of Congress' physician amendment[176] and passed laws effectuating an intent to close a loophole by widening the scope of the statutes.

A potential exists for misreading the scope of the statutes that are silent regarding physicians. Because the federal amendment was couched in terms of a physician exemption — "a certificate of need shall not be required for the acquisition of major medical equipment which will not be owned by or located in a health care facility unless . . . the equipment will be used to provide services to inpatients of a hospital"[177] — it might appear that statutes not containing similar provisions include physicians. Legislative history of the amendment reveals, however, that Congress was concerned that the statute, as originally written, excluded physicians.[178] The amendment, although phrased as an exemption, was an expansion of CON coverage to physicians in particular circumstances — the servicing of hospital inpatients. It would be incorrect to infer from the amendment's language that the statute, when silent on physicians, applied to physicians.

Where state statutes are silent regarding physicians, or

174. *See supra* text accompanying notes 49-55.
175. *See supra* notes 81-83 and accompanying text.
176. *See supra* notes 49-55 and accompanying text.
177. 42 U.S.C. § 300m-6(e)(1)(A) (1982).
178. *See supra* text accompanying notes 49-55.

specifically exclude physicians, the legislatures have decided, whether by choice or by neglect, not to extend their CON coverage to physicians. It is in these states that opportunity exists for health care facilities to work in concert with physicians to avoid review.

*Radiological Society of New Jersey v. New Jersey State Department of Health, Hospital Rate Setting Commission*[179] provides an illustration of such collaboration between a health care facility and a private physician. The failure in that case to circumvent the CON requirement resulted from the court's willingness to rely on a state regulation that extended CON coverage to acquisitions of major medical equipment not owned by or located in a health care facility, but used to serve the patients of a health care facility.[180] The court's reliance on this regulation, however, was misplaced because the regulation was not authorized by the state statute.

While the court correctly interpreted the intent of the 1979 federal amendment to broaden the scope of CON to all acquisitions used for inpatients, the court improperly viewed the amendment to the federal statute as authorization for the New Jersey *state regulation.*[181] When confronted with evidence that a loophole in the NHPRDA was permitting avoidance of CON review,[182] Congress acted to amend its statute. The Department of Health and Human Services then acted to amend its regulations to conform to the statutory amendment.[183] Faced with this mandate from the federal government to extend CON coverage,

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179. 208 N.J. Super. 548, 506 A.2d 755 (1986). *See supra* notes 149-54 and accompanying text.

180. *See supra* note 152.

181. "In an effort to comply with this minimum federal requirement, the New Jersey Department of Health revised its regulations for the certificate of need program on August 6, 1981." 208 N.J. Super. at 554, 506 A.2d at 757.

182. *See supra* text accompanying note 49.

183. State CON programs must apply to acquisitions of major medical equipment that will be located in a health care facility, and to

> acquisition[s] by any person of major medical equipment not owned by or located in a health care facility, if (A) the notice of intent required by § 123.406(a) is not filed in accordance with that paragraph, or (B) the State Agency finds, within 30 days after the date it receives a notice in accordance with § 123.406(a), that the equipment will be used to provide services for inpatients of a hospital.

42 C.F.R. § 123.404(a)(4)(ii) (1985).

many states amended their statutes.[184] New Jersey, however, was not among these states. Its legislature never made the decision to amend its CON *statute* to comport with the federal statute. Instead, the New Jersey Department of Health usurped state legislative authority by amending its own *regulations*.[185] If all that was necessary was a change in department regulations, one wonders why a substantial number of states and the United States Congress went through the extensive legislative process of amending their statutes. Where the New Jersey legislature had the federal model before it and did not follow that model, it is unreasonable to infer that the legislature intended its statute to be interpreted as though it did follow the federal model.[186]

The NHPRDA was a mandate to the states to enact CON legislation, as well as a model for that legislation. The federal statute itself was not addressed to health care providers and placed no demands on them. These demands could be made only by the individual states in the exercise of their police power.[187]

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184. *See supra* note 83.

185. Ohio joins New Jersey in having a regulation covering physicians acquiring major medical equipment for use with inpatients, without having a statutory provision specifically authorizing the regulation. OHIO ADMIN. CODE § 3701-12-05(D)(2)(b) (undated). Ohio differs significantly from New Jersey in that the Ohio legislature wrote into its statute a provision indicating its intent that the Ohio law conform to the federal. OHIO REV. CODE ANN. § 3702.52(A), (B) (Anderson 1980 & Supp. 1985). Ohio's regulation covering physician acquisitions may be authorized by this umbrella statutory provision. A caveat, however, applies to all Ohio's CON regulations: "For many reasons, the rules do not comport with the statute. As you are aware, the statute takes precedence over the rules when there is a conflict." Letter from Louis Pomerantz, Ohio State Dep't of Health, to author (Sept. 23, 1986).

186. A situation analogous to *Radiological* arose in New York. Peck v. Whalen, N.Y.L.J., Apr. 8, 1980, at 10, col. 5 (Sup. Ct. Westchester County 1980). In the New York dispute, the state agency had ordered a physician partnership to cease operation of a CAT scanner that it had purchased without obtaining a CON, and that it had installed on premises leased from a hospital. The court found that the state agency had no authority to act against the physician partnership because New York's statute applied only to hospitals. Justice Slifkin criticized the agency for "confus[ing its] supervisory functions with legislative functions." *Id.* at col. 7.

187. *See supra* note 39 and accompanying text (discussing constitutionality of CON legislation).

The NHPRDA acknowledged the need for state authorization of state agency actions in its requirement that the state programs "contain or be supported by satisfactory evidence that the State Agency has *under State law* the authority to carry out such functions . . . ." 42 U.S.C. § 300m-1(b)(2) (1982) (emphasis added).

The *Radiological*[188] court and the New Jersey health agency failed to recognize this distinction and confused federal statutory authority with state statutory authority. The court upheld the agency's reliance on a regulation that it had promulgated and that gave the Health Commissioner the right to disapprove reimbursement for the purchase by a health care facility of services from a vendor who is in violation of state or *federal* CON regulations.[189]

This agency regulation assumes that it is theoretically possible for one who sells services to health care facilities to violate *federal* CON regulations. It is an indispensable precondition to being found in violation of a requirement that one be subject to that requirement. Since, however, the federal CON statute, and regulations promulgated pursuant to that statute, made demands of the states and not of individual health care providers or their vendors, only the states can violate the federal regulations. The assumption that it is possible for one who sells services to health care providers to violate federal CON regulations is, therefore, fallacious.

The New Jersey court would have been wiser had it examined the New York courts' decisions[190] to refuse to *read* into their statute a requirement that the state legislature failed to *write* into the statute.[191]

In New York, the legislature has been given several opportunities to amend its statute and has declined.[192] In 1986, a bill

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188. 208 N.J. Super. 548, 506 A.2d 755 (1986).

189. "The Commission shall have the right to disapprove reimbursement for services purchased from vendors that are in violation of State or Federal certificate of need regulations." *Id.* at 555, 506 A.2d at 758 (citing N.J. ADMIN. CODE tit. 8, § 31B-4.32(d)).

190. *See supra* text accompanying notes 116-48. *See also supra* note 186.

191. Alaska's statute resembles New Jersey's in that it excludes private physicians. *See* ALASKA STAT. § 18.07.111(9)(B) (1986). In response to an inquiry Alaska's Attorney General declared that a group of physicians leasing space from a hospital for MRI equipment is exempt from the CON requirement where the leased space is adjacent, but not attached, to the hospital; the hospital is not involved in the purchase of the MRI; and the hospital's patients contract directly with the physicians for the MRI services. The Attorney General declared that until Alaska's legislature amended its statute, this acquisition would be exempt from review. 1985 Op. Alaska Att'y Gen. (Feb. 11, 1985) (LEXIS, states library, Alaska file).

192. "[E]fforts in recent years to bring privately owned equipment used on hospital inpatients within the State's CON requirements have consistently failed to obtain legislative approval." Clifton Springs Sanitarium Co. v. Axelrod, 115 A.D.2d 949, 950, 497

was introduced in the New York State Assembly that would make certain acquisitions by individual doctors subject to the same CON review to which hospitals are subject.[193] This legislation would have amended New York's CON statute[194] to require prior approval for the acquisition, through purchase, lease, or donation, of major medical equipment in excess of $400,000, by any health provider, not merely by institutional providers.[195] The bill would exempt from its requirements units of equipment that are individually below $400,000, but in the aggregate above $400,000, when they are acquired by a doctor who is establishing an office.[196]

The New York State Department of Health, at whose behest the bill was introduced, believed that an amendment was necessary because the unregulated sector has made increasing purchases of major medical equipment, and thus, has counteracted the state's efforts at centralization.[197] Of particular concern to the bill's supporters was what they perceived to be the premature proliferation of MRI equipment, the efficacy of which the state is still studying.[198]

This bill was never reported out of the Assembly's health committee, to which it had been referred.[199] It failed to receive any significant support from the medical community. Private physicians are not likely to welcome such regulation. From the perspective of the hospitals, the proposal would eliminate the presently unregulated sector as a source of competition, but it would also eliminate a significant method by which the hospitals can avoid CON review.

By going further in the coverage of physicians than the federal law, the New York proposal would avoid an inequity that some health planners noticed in the federal law. Frequently, agencies evaluating a hospital's CON application are forced to

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N.Y.S.2d 525, 527 (4th Dep't 1985).

193. N.Y.A. 10448, 209th Sess. (1986).

194. N.Y. PUB. HEALTH LAW §§ 2800-2802 (McKinney 1985).

195. N.Y.A. 10448, § 1.1, 209th Sess. (1986).

196. *Id.* § 1.7.

197. Draft Memorandum of State Dep't of Health, Feb. 24, 1986.

198. *Id.*

199. LEGISLATIVE BILL DRAFTING COMM'N, STATE OF NEW YORK LEGISLATIVE DIGEST 1986 A725.

deny the application because the proposed acquisition will provide a service that is already being offered in the area by a private physician acting independently of the hospital.[200] It may well be that the proposed service is one that would be provided more appropriately in the hospital environment than in a physician's office.[201] If the agency were to approve the acquisition by the hospital, it would be encouraging the oversupply of expensive medical equipment that it is required to prevent.

## VI. Efficacy of CON

Where states have written their statutes to make circumvention possible, institutional health care providers have attempted to take advantage of the opportunities created. Whether it is desirable to close the loopholes that permit circumvention of the CON process is a policy decision that should be made only after an evaluation of the efficacy of the process. If the process does not make a significant contribution toward cost containment and equitable distribution of health care resources and if it provides, as some critics suggest, an obstacle to improved health care,[202] it may be that the CON requirement should be abandoned.[203]

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200. Price, *Health Systems Agencies and Peer Review: Experiments in Regulating the Delivery of Health Care*, in LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS 373 (R. Roemer & G. McKray, eds. 1980).

201. *Id.*

202. One health care professional has pointed to the CAT scanner experience as demonstrative of the negative impact that the CON process can have on the quality of health care.

> As now structured, the CON process is not well suited to control the allocation of expensive new technologies in a community. An example is the introduction of the computerized axial tomography (CAT) scanner, which has revolutionized radiology in the past five years. The rate of development of knowledge about CAT scanning has far outstripped the capacity of the regulatory process to adjust to new information. Regulations in this field were obsolete even before formal promulgation. The need for research on the use of the CAT scanner and research using this new technology are not recognized in regulations. Research thus foregone may to an indeterminate degree adversely affect the quality of care for years to come.

Covell, *The Impact of Regulation on Health Care Quality*, in REGULATING HEALTH CARE: THE STRUGGLE FOR CONTROL 114-15 (A. Levin ed. 1980).

203. There has been no scarcity of proposals for alternatives or supplements to CON. One example is the prospective payment system first adopted in New Jersey in 1980. With Medicare expenses growing at an annual rate of approximately 15% since

Viewed in terms of equitable distribution of health care resources, the effect of the CON process has been limited. There is little evidence that HSA's have initiated programs for underserved areas. HSA's are largely reactive. When reviewing batched applications,[204] an HSA may grant approval to the project that will best meet the needs of a traditionally underserved population,[205] but, if no application is made, the HSA does not, on its own, institute a program.[206]

Success of the CON process in cost containment is similarly questionable. Health care costs continue to grow.[207] For the years 1965 through 1970, prior to the federal CON requirement, the medical components of the Consumer Price Index (CPI) grew at an annual rate of 6.1%, while the non-medical CPI grew at a rate of 4.1%. For 1982 through 1983, when the CON process was firmly in place and its full effects should have been apparent, the medical component was 8.7% while the non-medical CPI grew at a minimal annual rate of 2.9%.[208] Thus, even with CON, health care costs are growing at a substantially greater rate than the rest of the economy. The extent to which CON has kept health care costs from growing at an even faster rate remains to be established.

The *possibility* of eliminating annual increases in the cost

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1978, the federal government began experimenting with a program resembling New Jersey's in 1983. In a prospective payment system, fees received by a hospital for caring for a patient are set in advance of the treatment, according to diagnosis. The federal program affects only Medicare payments. R. BUCHANAN & J. MINOR, LEGAL ASPECTS OF HEALTH CARE REIMBURSEMENT 23 (1985). *See also* Enthoven & Noll, *Prospective Payment: Will It Solve Medicare's Financial Problem?*, 1 ISSUES SCI. & TECH. 101 (1984) (critiquing the prospective payment system along with alternate proposals for cost containment).

While some proposals, such as the prospective payment system, involve regulation, others involve a degree of deregulation, in the belief that competitive market forces can achieve an appropriate solution to health care distribution and cost problems. *See generally* INCENTIVES VS. CONTROLS IN HEALTH POLICY (J. Meyer ed. 1985).

204. *See supra* note 90 and accompanying text.

205. *See supra* text accompanying note 56.

206. New Hampshire is an exception to the reactive nature of HSA's. When its Health Service Planning and Review Board determines that there is a need for additional health services, it publishes a request for the submission of applications. Only those applications made in response to such requests are considered. N.H. REV. STAT. ANN. § 151-C:8(I) (Supp. 1986).

207. *See supra* note 1 and accompanying text.

208. NATIONAL CENTER FOR HEALTH STATISTICS, HEALTH UNITED STATES 127 (1985).

of health care, or of holding the increases to modest levels, is uncertain. One prominent physician suggests that all our efforts to lower the cost of medical care through elimination of inefficiencies and unnecessary procedures will still produce an annual rise in health care costs of close to 7%. Of this amount, 3.5% represents technological change, while the remaining increase can be attributed to population growth and to the labor intensive characteristic of the industry.[209]

The enormous expenditure of time and money by both administrative agencies and health care providers in complying with the CON process substantially reduces any savings that might be attributable to it.[210] For all its promise, CON review has resulted in the elimination of few projects. Of over 20,000 CON applications reviewed throughout the country between 1979 and 1981, only ten percent were ultimately disapproved.[211] Such statistics prompt understandable concern as to the wisdom of continuing to invest significant amounts of time, money, and effort on the CON process.

It has been suggested that the CON process actually increases the cost of providing health care.[212] By delaying investments, the CON requirement guarantees inflation-induced increases in costs. The substitution of expensive labor for capital investment in an already labor intensive industry increases total health care costs. By discouraging the entry of new providers, giving, in effect, a franchise to existing providers, CON elimi-

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209. Schwartz, *The Inevitable Failure of Current Cost-Containment Strategies*, in J. A.M.A. 220, 221-22 (1987).

Dr. Schwartz argues that "even if all useless care were gradually eliminated, we could anticipate only a temporary respite from rising costs unless the forces sustaining the real rate of change — chiefly technologic innovation and rising input prices — were simultaneously brought under control." *Id.* at 220-21. However, "[i]f . . . the essence of cost containment hinges on limiting the introduction and diffusion of *beneficial* new technology, there must eventually be some kind of society-wide decision that this is a necessary step." *Id.* at 223 (emphasis added).

210. *See* P. JOSKOW, *supra* note 21, at 84-85.

211. REPORT TO CONGRESS, *supra* note 8, at 48. This figure, however, represents only the percent of filed applications that were rejected and not the percent of dollar expenditures rejected. This figure may be tempered by the fact that the prospect of CON review may dissuade hospital administrators from developing plans for projects they anticipate will be rejected. The result, however, may not be entirely salutary because among the abandoned projects may be ones of great value to the quality of health care.

212. *Id.* at 124-25.

nates competition and the restraining effect that competition can have on prices.[213]

Even if a highly restrictive CON approach would effectuate large expenditure reductions, it would also have the potential for creating problems of excess demand and of hostility from patients who believe that their health care needs are no longer being met.[214] While health care regulators seek to rationalize the health care system, health care consumers want to feel that when family members fall ill, they will have convenient access to the best and most technologically advanced medical care. Attempts to regulate availability of resources create a tension between health care consumers and providers on the one hand, and health care regulators on the other.[215]

CON may be an unnecessary burden in states that regulate hospital fees.[216] If a service is underutilized and the loss cannot be spread over other services, good management should dictate its elimination or curtailment without the intervention of the CON process.[217]

## VII. Conclusion

The elimination of Title XV of the Public Health Service Act[218] compels states to reassess their CON programs and the overall health planning programs of which they are a part. Having lost the federal funding for these health planning programs, the individual states must determine whether to continue the programs entirely at state and local expense.

The lack of convincing evidence that CON programs make a significant contribution to health care cost containment, or to a more equitable distribution of health care resources,[219] suggests

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213. *Id.*

214. *See* P. JOSKOW, *supra* note 21, at 88-89.

215. D. ALTMAN, R. GREENE & H. SAPOLSKY, HEALTH PLANNING AND REGULATION: THE DECISION-MAKING PROCESS 153-54 (1981) (studying regulation and health planning in New England states).

216. Abernethy and Pearson attribute New York's relative success in eliminating underused facilities not to CON, but to the state's maintenance of reimbursement rates at levels that have forced some hospitals into bankruptcy. D. ABERNETHY & D. PEARSON, *supra* note 1, at 65.

217. *See supra* note 39.

218. *See supra* text accompanying note 11.

219. *See supra* notes 203-17 and accompanying text.

that states should develop and implement alternative approaches to solving these problems.[220]

Should a state determine, however, that CON programs have value and merit a role in the state's health planning scheme, the state must make a judgment regarding the scope of the program — the activities and providers that should be included. Current statutes must then be examined and refined to ensure that they are clear reflections of legislative intent. Where legislatures want their statutes to have a broad scope, covering a wide range of activities and providers, the statutes must be unambiguous expressions of this legislative intent in order to prevent subversion of the intent by health care providers employing circumvention techniques. Where the legislative intent is to narrow the scope of CON programs, legislatures have the responsibility to draft their statutes in such a manner that no opportunity is provided for the agencies administering the CON programs to overstep the intended boundaries.

Failure of legislatures to engage in this re-examination will result in continued circumvention of the law on the one hand, and overreaching by administrative agencies on the other. More importantly, failure to engage in a probing re-examination of the problems of rising health care costs and inequitable distribution of health care resources will create an even greater distance between those problems and their solutions.

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220. *See supra* note 203.