



UNC  
SCHOOL OF LAW

NORTH CAROLINA LAW REVIEW

---

Volume 57 | Number 6

Article 5

---

8-1-1979

# Making Certificate of Need Work

Michael K. Schonbrun

Follow this and additional works at: <http://scholarship.law.unc.edu/nclr>



Part of the [Law Commons](#)

---

## Recommended Citation

Michael K. Schonbrun, *Making Certificate of Need Work*, 57 N.C. L. REV. 1259 (1979).

Available at: <http://scholarship.law.unc.edu/nclr/vol57/iss6/5>

This Article is brought to you for free and open access by Carolina Law Scholarship Repository. It has been accepted for inclusion in North Carolina Law Review by an authorized administrator of Carolina Law Scholarship Repository. For more information, please contact [law\\_repository@unc.edu](mailto:law_repository@unc.edu).

# MAKING CERTIFICATE OF NEED WORK

MICHAEL K. SCHONBRUN†

Inflation in the last third of this century has become an obsession of the American polity.<sup>1</sup> Several factors, now widely accepted as causes of the country's inflation, have been cited repeatedly by economists, planners, industrial leaders and politicians in both major parties. Excessive government spending and over-regulation of business have been attacked, specifically the alleged high cost of complying with government regulations and the reported stifling of competition and innovation through the bureaucratization of key social and economic decisions.<sup>2</sup> The decline in productivity among American workers has also been cited,<sup>3</sup> while American consumers have been blamed for displaying little self-restraint in their purchasing and credit practices, for neglecting to take such preventive actions as installing proper home insulation, and for refusing to utilize efficient but inconvenient measures such as mass transit.<sup>4</sup> Inflation has also been attributed to the

---

† Vice President, National Jewish Hospital and Research Center/National Asthma Center, Denver, Colorado. Member, Ohio and Colorado bars. B.A. 1969, Yale University; J.D. 1973, University of Pennsylvania. The author is a former Assistant Director of the Colorado Department of Health, which is responsible for administering the Colorado Certificate of Need program and the Colorado State Health Planning and Development Agency (SHPDA) responsibilities. The views expressed herein are solely those of the author and do not represent the opinions or positions of the National Jewish Hospital and Research Center/National Asthma Center. Copyright © 1979 by Michael K. Schonbrun.

1. See, e.g., Silk, *Inflation: A Showdown Is At Hand*, N.Y. Times, Jan. 7, 1979, § 12, at 1. Silk, writing the lead story for the newspaper's year-end *National Economic Survey*, quoted President Carter's description of inflation as "the most complicated and intractable and corrosive problem of them all." *Id.* at 62.

2. See, e.g., Holsendolph, *Deregulation: Panacea or Pandora's Box?*, N.Y. Times, Jan. 7, 1979, § 12, at 28. Holsendolph cites a report by two economists at Washington University in St. Louis, Murray L. Weidenbaum and Robert DeFina, which found that in 1976 the total annual cost of federal regulation, including administrative costs and compliance costs, was \$66 billion and predicted that these costs would exceed \$103 billion by 1979. *Id.*

3. Worker productivity increased only 0.4% in 1978—consistent with the generally poor record of the last ten years when the productivity rate has risen only 1.6% a year—half the average annual growth rate in productivity experienced by American workers from 1947 to 1967. Workers' hourly compensation increased by 9.3% during the same period—the largest increase in 27 years. "Because that sharp rise was not offset by a large productivity gain, labor costs for producing goods and services rose 8.9 percent, the second largest increase ever." *Rocky Mountain News*, Jan. 27, 1979, at 76, col. 2.

4. See, e.g., Ettorre, *Consumers Pile Up Debt to Buy Homes, Furs, Autos*, N.Y. Times, Jan. 7, 1979, § 12, at 10. See also President Carter's speech, *The Energy Problem*, 15 WEEKLY COMP. OF PRES. DOC. 560 (Apr. 25, 1977).

rapid introduction into our society of gadgetry and technology and the accompanying advertising campaigns that present new but soon to be obsolete products in alluring packaging.<sup>5</sup> Finally, nonprofit institutions such as universities, community-based charitable collection services (United Way, Community Chest, etc.), and social welfare agencies have been hard hit by rising prices and have passed on these higher costs to their clients and benefactors.<sup>6</sup>

Many of these same forces operate in the health care sector of the economy. Indeed, with costs of health care rising 400 percent since 1965,<sup>7</sup> inflation of health care costs has exceeded even that of other sectors of the economy, leading President Carter to identify the containment of hospital costs as the leading priority in his administration's fight against inflation.<sup>8</sup> Since the advent of Medicare and Medicaid in 1965, government spending for personal health services has increased from 9.5 to 68.4 billion dollars in 1977—nearly seven fold.<sup>9</sup> New government bureaucracies and regulatory programs have burgeoned during the past ten years. The lack of price competition among hospitals has been frequently cited as a chief cause of inflation, together with the hegemony of the fee-for-service physician who serves as both the gatekeeper to the entire health care system and as a major economic beneficiary of this highly utilized system.<sup>10</sup> In addition, because of the now widely accepted principle that health care is a "right," immediate proximity to a full-service hospital has been widely, if inappropriately, regarded by the public as a necessity—thus providing a medical and quasi-legal rationale for the preexisting American penchant for convenience.<sup>11</sup>

---

5. See generally J. GALBRAITH, *THE NEW INDUSTRIAL STATE* (2d ed. 1977).

6. See generally Vladeck, *Why Non-Profits Go Broke*, *THE PUBLIC INTEREST*, Winter 1976, at 86.

7. Gibson & Fisher, *National Health Expenditures, Fiscal Year 1977*, *SOC. SEC. BULL.*, July 1978, at 5.

8. See Remarks by President Carter on the Administration's Hospital Cost-Containment Bill of 1979, 15 *WEEKLY COMP. OF PRES. DOC.* 383 (Mar. 6, 1979); the 1978 year-end interview of Hamilton Jordan, President Carter's Assistant for Political Affairs, who asserted that the "administration's biggest disappointments [were] ending 1978 without a peace treaty between Israel and Egypt and starting 1979 without a law putting a lid on hospital costs." *Rocky Mountain News*, Dec. 29, 1978, at 1, col. 1.

9. Gibson & Fisher, *supra* note 7, at 5.

10. See Enthoven, *Consumer-Choice Health Plan*, 298 *NEW ENGLAND J. MED.* 650 (1978). See also Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need,"* 59 *VA. L. REV.* 1143, 1155-69 (1973).

11. See, e.g., LOUIS HARRIS & ASSOCS., INC., *HOSPITAL CARE IN AMERICA* (1978) [hereinafter cited as LOUIS HARRIS POLL]. When queried whether they would be willing to pay a higher hospital bill out of their own pocket to keep a specific service in their *closest neighborhood* hospi-

Furthermore, for better or worse, the health care system is now highly dependent on technology.<sup>12</sup> It is a system whose primary institutions, hospitals, are nonprofit.<sup>13</sup> It is labor intensive, employing over 4.6 million people,<sup>14</sup> and it represents one of the few sectors in the American society in which recent labor organizing efforts have been successful and in which blue-collar workers have enjoyed real salary improvements in the past decade.<sup>15</sup> Finally, the health care industry itself is not only politically well organized with such national lobbying and trade organizations as the American Medical Association, the American Hospital Association, and the Blue Cross Association, but its constituents—most notably doctors, hospital trustees, and insurance company executives—are often the civic cornerstones of the nation's communities. Individually as well as collectively, they exercise great power as local opinion leaders.

It is into this highly inflationary, complex and politically volatile industry that new regulatory programs such as certificate of need, prospective rate review, and medical peer review (PSROs) have been introduced. These programs are designed to inject considerations of efficiency, effectiveness and equity into the health care industry. It is no small order, especially at a time when public mistrust of governmental programs is high.<sup>16</sup>

The basic premise of the health reformers, champions of these programs, is that there is substantial waste and inefficiency in the health system and that, if left alone, the dysfunctions of the system will con-

---

tal, the respondents said yes to each of the following services: cardiac care unit (76% of respondents), emergency room (73%), kidney machines for renal dialysis (62%), open heart surgery (59%), cancer therapy (56%), and CAT scanner (53%). *Id.* at 85.

12. See generally Iglehart, *The Cost and Regulation of Medical Technology: Future Policy Directions*, 55 MILBANK MEM. FUND Q. 25 (1977).

13. In 1976, 89% of the beds and 87% of the country's nonfederal short-term general and other special hospitals were nonprofit. AMERICAN HOSPITAL ASSOCIATION GUIDE TO THE HEALTH CARE FIELD 7-9 (1977). Based on industry-supplied figures, nonprofit hospitals in some states are struggling financially. Four out of every five nonprofit hospitals in New York State sustained an operating loss in 1977. Newsletter of Colorado Chapter, Hospital Financial Management Association, February 12, 1979.

14. Television interview with Dr. James Sammon, Executive Vice President of the American Medical Association, broadcast on Channel 3, New York City (Jan. 20, 1978, 6:30 p.m.).

15. From 1966 to 1975, the average annual rate of increase in earnings for hourly workers in hospital settings was 8.7%, compared to 5.8% for comparable workers in other non-farm settings. M. FELDSSTEIN & A. TAYLOR, *THE RAPID RISE IN HOSPITAL COSTS* (Council for Wage and Price Stability 1977).

16. LOUIS HARRIS POLL, *supra* note 11, at 56. The poll showed that 46% of respondents were opposed to additional government regulation, 38% were in favor, and 16% were not sure. Interestingly, of those who were patients within the year, 42% were in favor, 41% opposed, and 17% not sure.

tinue unabated.<sup>17</sup> The reformers hold that the costs of providing good quality health services can and should be cut back or at least redirected and controlled. They cite the lack of correlation between per capita expenditures and health status, the regional differences in hospital length-of-stay and admission rate per capita, which show little relationship to mortality or morbidity figures, and the notable discrepancies in per capita expenditure levels and utilization rates between organized prepaid group practices and the still dominant fee-for-service delivery system.<sup>18</sup>

This article will indicate how one of these new regulatory programs—certificate of need—can be employed to help rationalize the American health care delivery system. The author recognizes the pervasiveness, longevity and multiple origins of the current American inflation, the established structural facts about the American health care system (for example, the continued predominance of the fee-for-service system), and the prevailing skepticism about governmental regulatory programs marked, in part, by the recent rebirth of “free market” strategists and “antitrusters.”<sup>19</sup> Consequently, the policy initiatives proposed here will be compatible with both the realities of the American health care scene and the current predispositions of the American public and its political, economic and community leaders.<sup>20</sup>

---

17. See, e.g., Remarks of Joseph A. Califano, Jr., before the National Academy of Sciences, Washington, D.C., October 26, 1978, at 11-15 (U.S. Government Printing Office 1978) [hereinafter cited as Remarks of Joseph A. Califano].

18. See, e.g., Bunker, *Surgical Manpower*, 282 NEW ENGLAND J. MED. 135 (1970). See also *Getting Ready for National Health Insurance: Unnecessary Surgery, Hearings Before the Subcomm. on Oversight and Investigations of the Comm. on Interstate and Foreign Commerce, House of Representatives*, 94th Cong., 1st Sess. 73-87 (1975) (testimony and statement of John Wennberg); Gaus, Cooper & Hirschman, *Contrasts in HMO and Fee-for-Service Performance*, SOC. SEC. BULL., May 1976, at 3; Lembcke, *Measuring the Quality of Medical Care Through Vital Statistics Based on Hospital Service Areas: 1. Comparative Study of Appendectomy Rates*, 42 AM. J. PUB. HEALTH 276 (1952).

19. See Iglehart, *Adding a Dose of Competition to the Health Care Industry*, 10 NAT'L J. 1602 (1978). Iglehart provides a brief historical account of the new interest in the health care sector of the Federal Trade Commission and the Justice Department's Antitrust Division, and quotes FTC Chairman Michael Pertschuk's explanation for his agency's recent activity: "The commission—like most other agencies of government—was slow to admit that one possible way to control the seemingly uncontrollable health sector could be to treat it as a business and make it respond to the same marketplace influences as other American businesses and industries." *Id.* See generally Enthoven, *supra* note 10; Havighurst, *supra* note 10.

20. See generally Marmor, Wittman & Heagy, *Politics, Public Policy, and Medical Inflation*, in HEALTH: A VICTIM OR CAUSE OF INFLATION (M. Zubkoff ed. 1976); see also Demkovich, *Health Planning Agencies Face Threat From Deregulators*, 11 NAT'L J. 687 (1979); Iglehart, *Why Hospitals Are Waging War on Regulations*, 11 NAT'L J. 20 (1979).

## I. THE CERTIFICATE OF NEED MECHANISM

Certificate of need (CON) was first introduced in this country in 1964 in New York, and similar programs are now operating in all states except Missouri.<sup>21</sup> Most commentators assert that the primary motivation for CON enactment in New York and its subsequent passage in other states was cost containment. The salutary effect of the mechanism on health care inflation occurs, its advocates state, by limiting the effects of "Roemer's law."<sup>22</sup> Roemer postulated that, because of the lack of price competition, the lack of discriminating consumer behavior, and the pervasiveness of third-party coverage in the health marketplace, a "bed built was a bed filled," regardless of community need, financial feasibility, or impact on quality of care.<sup>23</sup> While highly controversial at the time of its initial pronouncement, Roemer's law is now widely accepted. By preventing unnecessary capital expenditures, not only can the cost of the initial construction or acquisition be saved, but also the accompanying operating expenses. For example, it has been estimated that the operating cost for every new piece of equipment will equal the original cost in a period of two to two and one-half years, and for the CAT scanner, the first-year operating cost alone may equal or exceed the purchase cost.<sup>24</sup>

The mechanisms of CON<sup>25</sup> vary from state to state. Its fundamen-

---

21. CHAYET & SONNENREICH, P.C., CERTIFICATE OF NEED: AN EXPANDING REGULATORY CONCEPT 5-6 (1978).

22. See generally W. McCLURE, REDUCING EXCESS HOSPITAL CAPACITY (1976); INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES, CONTROLLING THE SUPPLY OF HOSPITAL BEDS 7-16 (1976).

23. Roemer, *Bed Supply and Hospital Utilization*, HOSPITALS, November 1, 1961, at 36. See also Wennberg & Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102 (1973). But see M. FELDSTEIN, ECONOMIC ANALYSIS FOR HEALTH SERVICE EFFICIENCY 201-221 (1968); INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES, *supra* note 22, at 18.

24. Somers & Somers, *A Proposed Framework for Health and Health Care Policies*, 14 INQUIRY 115, 153 (1977).

25. Unless otherwise indicated, the term "certificate of need" (CON) will be used in its broadest sense, referring to the generic kind of regulatory control that is being exercised over capital expenditures; consequently, state CON statutes, the federal 1122 review program (Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1386 (codified at 42 U.S.C. § 1320a-1 (1976))), and even those reviews backed by sanctions in conformance clauses of privately sponsored reimbursement contracts (most notably those developed by miscellaneous Blue Cross plans) will all be included in the review. Because of requirements in the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (codified at 42 U.S.C. §§ 300k-300t (1976)), with which states must comply by 1980, and the anticipated repeal of the 1122 program (promised by HEW to occur when states comply with the planning act's standards), the federal CON procedures and standards most frequently cited in this article will be based on the requirements of 42 U.S.C. §§ 300m-300t (1976). The analysis will not be limited, however, to the federal requirements, since only seven states had federally conforming programs as of October 1978 and most of the nation's experience with CON has been with a wide range of systems. Fur-

tal principles, however, are generally uniform and entail administrative procedures basically analogous to those involved in issuing permits or licenses. A CON is essentially a license required by the state before certain types of medical care projects may be initiated. The CON process is composed of several stages. A project is initiated by a health care provider, customarily an institutional provider, although physician offices have been included in several state laws. It is then submitted to the reviewing agency, either an agency of state government or the quasi-governmental health systems agency (HSA), for approval. In many states, such as Colorado, projects are submitted concurrently to both; the division of authority between the two, however, is not always clear.

After a determination that the project is subject to review (it exceeds a specific dollar threshold, it is not subject to a "grandfather" clause, etc.), the substantive review of the project's merit commences. Within a fixed time period (now ninety days under P.L. 93-641<sup>26</sup>), the project is reviewed for conformity with existing standards, criteria and plans that under the tenets of health planning stand as the basic measuring instruments used to evaluate community need. Specifically, it is studied for financial feasibility and for its effect on prevailing community health costs and quality and availability of care. In some states, including Colorado, the burden of proof is clearly on the proponent of the project. In other states, the location of the burden of proof is not clear.<sup>27</sup> Under the provisions of P.L. 93-641, the burden will clearly be on the project's proponent, at least for inpatient hospital services.<sup>28</sup>

Under CON statutes all licensed hospitals and, in most states, all licensed nursing homes are subject to review regardless of the source of financing for the project.<sup>29</sup> Failure to obtain a CON renders the provider subject to such sanctions as loss of license, injunctive proscription and ineligibility for payment from some or all third-party payors.

The CON process is generally classified as adjudicatory.<sup>30</sup>

---

thermore, this article will focus on the hospital sector—the most inflationary part of the health care industry—where CON controls have been used longer and more extensively than elsewhere.

26. National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300t (1976)).

27. See generally Bovbjerg, *Problems and Prospects for Health Planning: The Importance of Incentives, Standards, and Procedures in Certificate of Need*, 1978 UTAH L. REV. 83, 118-120.

28. See 42 C.F.R. § 122.309 (1978).

29. North Carolina *ex rel. Morrow v. Califano*, 445 F. Supp. 532 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978); see CHAYET & SONNENREICH, P.C., *supra* note 21, at 9-11.

30. See, e.g., *Minnesota State Bd. of Health v. Governor's Certificate of Need Appeal Bd.*, 304 Minn. 209, 213, 230 N.W.2d 176, 180 (1975).

Whether CON should be an adversarial rather than a consultative process, however, remains a hotly debated issue in many states, especially among providers. Opponents of an adversarial system are concerned about the length of time it would take to conduct full-blown evidentiary hearings (including rights of cross-examination) for each of the several CON cases decided monthly by the CON decisionmaker. There is also an apprehension about excessive legalism that is common not only among health providers but also among many veterans of health planning activities who were reared on the "cooperative" model of health planning and trained in methods of community organization. It is feared that a shift to full evidentiary hearings would bring conflict-oriented decisionmaking rather than the consensus-oriented model that has dominated the largely voluntary, nonprofit health care sector.<sup>31</sup> It is also feared that the shift would result in a transfer of control over the health care system from the health providers and professionals to the lawyers. Proponents of the adversarial approach, on the other hand, question whether lawyers—or traditional legal process—can or should be kept out of a decisionmaking system that often involves multimillion dollar decisions, complex statutory procedures, and the future of long established, resource intensive and popularly supported institutions.

Appeals of decisions adverse to the applicant have been granted as a matter of right. Under the provisions of P.L. 93-641, an HSA also has standing to appeal a decision made by the state CON decisionmaker that is contrary to its recommendation.<sup>32</sup> Administrative remedies are generally required to be exhausted before judicial review can be obtained, but the latter is typically granted pursuant to the state's administrative procedure act (APA). The applicability of the state's APA to the procedures of the earlier HSA review remains an unsettled legal issue. Furthermore, the standing of parties other than the proponent and the HSA to appeal a decision adverse to their interests is increasingly a matter of debate; few state CON statutes presently provide for broad standing.<sup>33</sup>

---

31. "The idea was that if providers were brought together and properly informed, they would come to appreciate the mutuality of interests among them and with the communities they served. With technical assistance furnished by the planning agency, each hospital would willingly plan for its own development." Klarman, *Health Planning: Progress, Prospects and Issues*, 56 MILBANK MEM. FUND Q. 78, 88 (1978). See also Gottlieb, *Certificate of Need: Potential Threat to Planning*, HOSPITALS, December 16, 1971, at 51.

32. 42 U.S.C. § 300m-1(b)(13) (1976). See generally Dolan, *Who Has Standing to Appeal Certificate-of-Need Decisions?*, 1978 UTAH L. REV. 155.

33. See generally Dolan, *supra* note 32.



A CON generally must be exercised within specific time periods (for example, binding contracts must be entered into by the provider to commence the project within twelve months) and must be consistent with the terms of the application (for example, a piece of equipment estimated in the application to cost \$500,000 and approved on that basis should not cost the provider \$1 million at the actual time of acquisition).<sup>34</sup> A CON has been regarded as not otherwise subject to limitation after approval, however, and little monitoring is currently being done to assure compliance with the terms of the CON decision or the representations made by the project proponent in the CON application.

## II. PAST APPRAISALS OF CERTIFICATE OF NEED PROGRAMS

### A. *The Majority View: "A Failure"*

Despite strong advocacy of the CON program by the Carter Administration, leading senators and congressmen, and such private sector representatives as business and labor groups, insurance companies, and even provider groups themselves,<sup>35</sup> the majority view is that the program has, to date, been a failure.<sup>36</sup> The most damaging piece of evidence in support of this conclusion is the extremely high approval rate in those states with CON programs—the great majority of all projects submitted for review have been approved.<sup>37</sup> In addition, "grandfather" provisions incorporated into most state CON statutes to protect those projects already commenced from ex post facto reviews may have spurred many providers to accelerate plans for expansion prior to the law's passage, and may have even led to a rebirth of projects previously shelved by the providers themselves.<sup>38</sup>

---

34. See, e.g., COLO. REV. STAT. § 25-3-509 (Cum. Supp. 1978).

35. State hospital associations have tended to support efforts to enact CON laws, giving rise to speculation by some observers that CON programs will result in a pro-industry anti-consumer bias helping to preserve health care cartels and protecting them from competition. See, e.g., Havighurst, *Franchising Experience from Other Industries and its Relevance for the Health Field*, in MANAGEMENT MEMORANDUM ON HOSPITAL FRANCHISING (1973).

36. See, e.g., LEWIN & ASSOCIATES, INC., EVALUATION OF THE EFFICIENCY AND EFFECTIVENESS OF THE SECTION 1122 REVIEW PROCESS (1975); Hellinger, *The Effect of Certificate-of-Need Legislation on Hospital Investment*, 13 INQUIRY 187 (1976); Salkever & Bice, *The Impact of Certificate-of-Need Controls on Hospital Investment*, 54 MILBANK MEM. FUND Q. 185 (1976).

37. A 1975 study indicated that 93% of all CON projects submitted to review in 20 states were approved. LEWIN & ASSOCIATES, INC., *supra* note 36. But see American Health Planning Association, *Selected Preliminary Results from a Survey of Health Planning Agencies: HSA Performance Under Certificate of Need and 1122 Programs* (Nov. 28, 1978) [hereinafter cited as American Health Planning Association report.]

38. The recent controversy in California regarding the passage of AB 4001 is the most visible

In states such as New York and Massachusetts, where the approval rate for CON has been lower than average and where reviews have been occurring for at least several years, the rate of health care inflation—especially in the hospital sector, the primary target of CON—continues to rise at rates substantially above the country's general inflation rate.<sup>39</sup> These findings tend to corroborate the results of a 1976 study by Bice and Salkever showing that from 1968 to 1972 (the early days of CON) the programs had no apparent effect on slowing the rate of overall hospital asset growth even though they were successfully reducing the rate of hospital bed growth. In addition, the study found a greater rate of asset growth in states with CON than in states without it. The authors concluded that hospitals were merely shifting new expenditures into areas immune from review, such as equipment and salaries.<sup>40</sup>

Another piece of evidence pointing toward the failure of the CON system is the inconsistency of the outcomes of review<sup>41</sup>—a significant defect in a regulatory system that must be judged by standards of fairness as well as stringency. Inconsistency arises from several causes: comparable projects may be handled differently by the relatively autonomous regional planning bodies within the states (now the HSAs, previously the CHP "b" agencies), which may well possess different levels of staff competence, adopt review standards and criteria of divergent stringency and scope, and be guided by boards with differing ori-

---

case in point. It has been estimated that \$2.7 billion in new capital expenditures resulted from the passage of AB 4001, a much tougher state CON law than the California program it replaced. This estimate has been challenged by the official responsible for the California program, who claimed that only \$150 million could be attributed to projects "generated or accelerated" to beat the new law's deadline, although he did concede that \$1 billion in projects had been grandfathered under the law's exemption of projects that would result in "substantial economic loss" if discontinued (the lesser of \$75,000 or 10% of the project total). Letter from Saleem A. Farag, Chief, Office of Statewide Health Planning and Development, to Dr. Stuart H. Shapiro, Office of United States Senator Edward M. Kennedy (Nov. 23, 1977). See CAL. HEALTH & SAFETY CODE § 437.11(b)(3) (West Supp. 1978).

39. See, e.g., Health Care Expenditures in Massachusetts, White Paper prepared by the Health Planning and Policy Group of the Commonwealth (June 9, 1978).

40. Salkever & Bice, *supra* note 36, at 206-09. See also Hellinger, *supra* note 36, at 191-92.

41. See, e.g., North Miami Gen. Hosp. v. Office of Community Medical Facilities, 355 So. 2d 1272, 1275, 1277 (Fla. Dist. Ct. App. 1978) (final administrative decision to deny a CON for a hospital to acquire a CAT scanner reversed, in part, because a CON for a CAT scanner had been granted to another hospital in the same county during the pendency of the application in question when the same standard for review—a 2400 scan per year utilization rate—had been in place and the other facility had failed to meet the standard). See also Northwest Hosp. v. Illinois Health Facilities Planning Bd., 59 Ill. App. 3d 221, 227-28, 375 N.E.2d 1327, 1332 (1978) (denial of application for new medical/surgical and intensive care beds reversed because the standard, created by defendant for use in ruling on plaintiff's application alone, was against substantial weight of the evidence).

entations (for example, one emphasizing accessibility of care, another focusing on cost containment). The state CON decisionmaker, should it decide to defer to frequently diverse regional recommendations, then renders different final decisions on comparable projects within the state.<sup>42</sup>

Temporal differences in project submission may also result in inconsistent decisions—for example, a project submitted before plans or criteria have been adopted or revised may well fare better than a comparable project submitted afterward. Similarly, a project that is submitted and approved may well be treated differently than a subsequent, comparable project if only because the first program has fully satisfied the identified need in the community for the service and the second project—however excellent the proponent's reputation for quality, cost-effectiveness and service to low-income individuals—is, therefore, regarded as redundant. This approach is consistent with precedent elsewhere in the field of law and public policy and can be defended as necessary and appropriate for a system that must not remain blindly tied to outdated approaches or allow unproductive duplication.<sup>43</sup>

Political interference can lead to favored treatment and consequently to inconsistent outcomes. The most notable of such efforts has occurred in Massachusetts, where the state legislature recently passed twelve special bills to grant CONs to twelve facilities whose applications had been denied by the state agency. Governor Dukakis vetoed all twelve bills, but the Massachusetts legislature succeeded in overriding two of the vetoes.<sup>44</sup> Several years earlier, a Massachusetts court reviewed two special bills passed by the state legislature to grant per-

---

42. The likelihood of this occurring depends, of course, on the diversity of the HSAs within the state, the perceived competence and political strength of the HSA and state agency, the nature of the project, and the scope of review and appeal rights under the state CON statute. The Arizona CON law, for example, requires the state decisionmaker to adopt the HSA's recommendation unless he finds that its findings are arbitrary, capricious or not supported by substantial evidence. ARIZ. REV. STAT. ANN. § 36-433.02 (West Supp. 1978). While the Arizona law is not typical and is not in conformity with the requirements of P.L. 93-641, it does illustrate the problem in other states where the state's scope of review of HSA actions may be limited, especially when a favorable action has been taken on the CON application. See also N.J. STAT. ANN. 26:2H-1 (West Supp. 1978); Somers & Somers, *Certificate of Need Regulation: The Case of New Jersey*, in REGIONALIZATION AND HEALTH POLICY (E. Ginzberg ed. 1977).

43. See, e.g., *Saint Joseph's Hosp. v. Finley*, 153 N.J. Super. 214, 225, 379 A.2d 467, 472 (1977), cert. denied, 75 N.J. 595, 384 A.2d 825 (1978), in which the court ruled that it was "entirely within [the] power and responsibility [of the CON Board] as a continuing regulatory body, in the light of present and future considerations in the public interest," to adopt new regional regulations regarding cardiac surgery units, despite prior determinations to the contrary.

44. HEALTH BRIEFS, September 1977 (prepared by the Massachusetts Office of State Health Planning).

mission to two hospitals to expand after their CON applications had been rejected by the state agency; the court determined that the legislative actions were lawful, having violated neither the federal nor the state constitution.<sup>45</sup>

The recent uproar in Oklahoma over the proposed Oral Roberts Hospital, in which a CON was sought for a \$250 million medical complex including a 777 bed hospital, illustrates the political issues lurking in CON reviews. In the Oral Roberts case the state CON decisionmaker, consisting of three state officials (all gubernatorial appointees), overrode the negative recommendation of the HSA after the state legislature, in the face of a massive letter writing campaign launched by Rev. Roberts, passed an unprecedented resolution supporting the project. The local HSA and several Tulsa hospitals have filed an appeal, and the decision is now being challenged in court.<sup>46</sup>

It should be noted parenthetically that all CON decisions are inherently political since they affect the allocation of scarce resources—money, staff and status.<sup>47</sup> In addition, given the reviewing agency's dependence on the legislature for state authorizations and appropriations for operating expenses (even if it is only for authorization to spend federal monies already received or allocation of the twenty-five percent state match required under P.L. 93-641), it is difficult to fault the sensitivity of CON reviewers within the executive branch to the concerns of influential state legislators. Nonetheless, it is a problem in the present CON system that has contributed to the lack of effectiveness of many state programs.<sup>48</sup>

Other inconsistencies may arise among comparable projects because of nonsubstantive differences in the quality of the project's advocacy as evidenced by the degree of professionalism of the written application or of the oral presentation submitted to the CON decisionmaker. Most of the costs incurred by a provider in developing and later presenting his CON proposal are reimbursable from patient

---

45. *Commissioner of Pub. Health v. Bessie M. Burke Mem. Hosp.*, 366 Mass. 734, 323 N.E.2d 309 (1975). See Weiner, *Participatory Procedure and Political Support for Hospital Cost Containment Programs: Limits of Open Administrative Process*, this Symposium, at text accompanying notes 114-27.

46. For a more complete description of surrounding events, see NEWSWEEK, May 8, 1978, at 43.

47. See text accompanying notes 127-49 *infra*.

48. The 1978 session of Congress considered, but did not introduce, amendments to P.L. 93-641 that would have withheld federal financial support from health programs in states where the legislature explicitly overrules an administrative CON decision; such an approach, however, would do little for situations in which political pressures are used more subtly.

sources, including public and private third-party payors. This fact tends to reward large urban facilities and penalize smaller rural facilities that have less access to consultants, a greater hesitancy to utilize "outsiders," and a smaller allocation of overhead funds that can be used at the institution's discretion.

Prior to 1975, many regional health planning bodies received direct financial support from providers and provider associations—the very institutions whose projects they were required to review under CON. The possibility thus arose for favored, inconsistent and obviously inappropriate reviews. Provisions of P.L. 93-641 now specifically prohibit CON review and health planning agencies from receiving such "tainted" money.<sup>49</sup>

In contrast to Bice and Salkover's examination of outcomes under CON, studies by Lewin and Associates examined CON procedures, structures and standards utilized in decisionmaking and found significant defects throughout the system.<sup>50</sup> Relatively few CON matters have reached the courts, but of those cases reported, several judicial decisions, based on findings of procedural irregularities, have resulted in reversals of CON decisions made at the administrative level. The most cited procedural errors have been the failure of the state CON reviewing agency to develop an adequate adjudicatory or rulemaking record<sup>51</sup> or to promulgate procedures and standards pursuant to the state's APA.<sup>52</sup> Some courts have also struck down CON decisions on

---

49. 42 U.S.C. § 3001-1(b)(5) (1976).

50. LEWIN & ASSOCIATES, INC., *supra* note 36; LEWIN & ASSOCIATES, INC., EVALUATION OF NEW YORK STATE'S CERTIFICATE OF NEED PROGRAM (1977).

51. *See* North Miami Gen. Hosp. v. Office of Community Medical Facilities, 355 So. 2d 1272, 1275 (Fla. Dist. Ct. App. 1978), in which the court found that the CON review standard of 2400 CAT scans per annum was not supported by "sufficient, competent and substantial" evidence.

52. *See* Nebraska Methodist Hosp. v. Casari, [1978 Transfer Binder] MEDICARE & MEDICAID GUIDE (CCH) ¶ 29,205 (D. Neb. Aug. 18, 1978), in which the disapproval of a \$28 million project by the CON agency (in this case the Designated Planning Agency under the 1122 program) was struck down because the agency had failed to promulgate valid regulations pursuant to state law. The court rendered this ruling even though the state agency had issued rules (though the state's APA had not been complied with) and was conducting the 1122 program pursuant not to any state law but in accord with a contract with the federal government. The court stated that the "federal government cannot authorize a state agency to act where it could not otherwise act." *Id.* at 10,306. *But see* St. Joseph's Hosp. v. Finley, 153 N.J. Super. 214, 379 A.2d 467 (1977), *cert. denied*, 75 N.J. 595, 384 A.2d 825 (1978). The *Casari* ruling may be in conflict with the Supreme Court's decision in North Carolina *ex rel. Morrow v. Califano*, 435 U.S. 962 (1978), which upheld the constitutionality of CON even as applied to a state where CON had been earlier ruled unconstitutional. *See also* *In re Certificate of Need for Aston Park Hosp., Inc.*, 282 N.C. 542, 193 S.E.2d 729 (1973). Furthermore, the court's ruling in *Casari* that no 1122 program can be implemented in a state until valid state regulations are promulgated is highly questionable; no other court has so

substantive grounds, specifically because of inconsistent treatment of comparable projects.<sup>53</sup>

Other concerns about CON have been raised, and although largely undocumented at the present time, they warrant a brief mention. CON staff have been described as underpaid and underutilized, with a high turnover rate, as exemplified, perhaps not suprisingly, by the Massachusetts experience in which there were four CON administrators during a recent three-year period.<sup>54</sup> Further, it was anticipated that CON would stifle innovation and result in cartelization of the health system;<sup>55</sup> however, no evidence has been adduced showing that health maintenance organizations (HMOs), out-patient surgicenters, or other innovative services have been prejudicially treated.<sup>56</sup> Finally, compliance with the CON process itself has been called inflationary because of the costs incurred in preparing and presenting a competent and comprehensive application.<sup>57</sup> As discussed above, costs incurred for such a purpose can be sizable (\$5,000 to \$10,000 is a recent estimate in Colorado), but they are reimbursable and are thus ultimately picked up by consumers and taxpayers.

### *B. The Minority View: "A Limited Success"*

The supporters of CON have been less effusive in praising the program than the critics have been vehement in damning it. Supporters believe that during the last two years there has been a substantial improvement in the quality and results of the program. They also believe that many of the program's recent successes still cannot be quantified.<sup>58</sup>

---

held since the 1122 program began in 1972. The decision has, nonetheless, prompted emergency rulemaking in at least one state, Colorado.

53. See note 41 *supra*.

54. Medeiros, *Long Range Institutional Plans and Budgets: Can They Provide a Vehicle for Anticipatory Strategies?*, in *LINKING HEALTH PLANNING AND REGULATION TO INCREASE COST EFFECTIVENESS* 14 (M. Sweetland & K. Bauer eds. 1977).

55. See, e.g., Havighurst, *supra* note 10.

56. See, e.g., LEWIN & ASSOCIATES, INC., *supra* note 36. See also text accompanying notes 103-04 *infra*.

57. D. KINZER, *HEALTH CONTROLS OUT OF CONTROL* 97 (1977).

58. See, e.g., Remarks of Joseph A. Califano, *supra* note 17, at 7-10. See the American Health Planning Association report, *supra* note 37, at 1-2, which cites an approval rate of 75% for all capital investment among those 134 of 203 HSAs surveyed (covering approximately 60% of the population), with alleged savings of over \$1 billion during 1976-1978. It is important to note, however, that the statistics covered not only formally submitted and finally determined projects but also "unofficial though documentable actions which led to the withdrawal or non-submission of CON/1122 applications." *Id.* The study is, by the admission of its own authors, very preliminary: its base data has not been verified; it covers neither the full universe of HSAs nor state agencies; no verification has been performed on the category labelled "unofficial but document-

Other proponents assert that CON has improved institutional planning within those facilities subject to its jurisdiction.<sup>59</sup> Many health institutions have underdeveloped internal planning capabilities and would clearly benefit from any program that required them to better define their present and future goals and objectives. Such internal planning may become increasingly necessary to justify a provider's CON applications and may help to rationalize a desired project in terms of established community goals. These planning efforts may also be useful to the facility in determining a tactically appropriate response to a CON application from a local or regional competitor.<sup>60</sup>

Finally, CON has been said to serve as a forum to make the general public, large purchasers of health care such as labor trust fund directors and corporate employee benefit managers, and the news media more aware of the forces driving up health care costs. This increased cost consciousness would result, it is argued, from bringing the reasons for and implications of expansionist health decisions out of the private boardroom of individual health institutions and insurance companies and into a public decisionmaking forum.<sup>61</sup>

### III. AN ASSESSMENT OF CURRENT CERTIFICATE OF NEED PROGRAMS

In P.L. 93-641 Congress attempted to spur the development of new state CON programs and the improvement of existing programs. Congress has also shown interest in amending federal legislation to ameliorate problems that continue to exist. But while the lure of federal dollars may have induced some improvement of the nation's CON programs, the inherent structural problems to be discussed in this section indicate that without substantial reform the prospects for effective CON efforts will remain dim.

The increase in federal funding to HSAs and state agencies under P.L. 93-641, and the prohibition against provider financial support to these agencies, may help assure more professional staff and end the

---

able" regarding withdrawn or never-submitted projects; and, most importantly, it fails to examine, as Bice and Salkever would require, whether the overall level of capital resources flowing into the hospital sector has stabilized or declined. See Salkever & Bice, *supra* note 36.

59. AMERICAN HOSPITAL ASSOCIATION, *THE PRACTICE OF PLANNING IN HEALTH CARE INSTITUTIONS*, 83-86 (1973). See also Peters, *L-R Planning May Direct Change*, Impact, December 26, 1978 (newsletter published by PACT Health Planning Center, Denver, Colorado).

60. See generally Medeiros, *supra* note 54, at 13-17.

61. See, e.g., Remarks of Joseph A. Califano, *supra* note 17, at 10.

"strings attached" funding for many regional CON agencies. Requiring facilities actively to explore "less expensive alternatives" and, as a precondition to granting a CON for projects involving in-patient services, forcing the CON decisionmaker to make written findings in as many as ten areas, should also prove beneficial in strengthening the CON process.<sup>62</sup> The emergence of the various plans<sup>63</sup> required under P.L. 93-641 may prove useful in conducting CON reviews, but only if they are of good quality—a very uncertain prospect.

Inadequate plans will only serve to bolster the CON cases of underserving applicants. If the plans are too generous, they will tend to show an inappropriate need for a project; if the plans are overly stringent, they may be attacked as arbitrary, capricious and lacking a rational basis and will generate sympathy for the CON applicant unless technical support for the plan can be summoned. This recently occurred in a Florida case involving the denial of a CON for a CAT scanner.<sup>64</sup> In denying the hospital's application the state CON reviewers invoked a utilization guideline of 2,400 scans per year for CAT scanners, a guideline recommended by the federal government.<sup>65</sup> A Florida appellate court reviewing the decision ruled not only that no rulemaking record had been developed by the CON agency to indicate whether any serious agency consideration had been given to the reasonableness of the utilization standards or their suitability to the proposed service area (the city of Miami) but also that use of the standard as the sole review criterion was inappropriate. Consequently, the court ruled in favor of the hospital and granted it the CON even though there were several scanners operating at less than capacity within a five mile radius of the hospital, far more than is generally thought appropriate.<sup>66</sup>

Moreover, given the general experience to date of inadequate consumer involvement and pervasive provider influence (if not de facto domination),<sup>67</sup> it is doubtful that the system being developed under the terms of P.L. 93-641 will provide the balanced political support needed

---

62. 42 C.F.R. § 123.410 (1977).

63. See text accompanying notes 86-107 *infra*. See also Atkisson & Grimes, *Health Planning in the United States: An Old Idea with a New Significance*, 1 J. HEALTH POL. POL'Y & L. 295 (1976).

64. *North Miami Gen. Hosp., Inc. v. Office of Community Medical Facilities*, 355 So. 2d 1272 (Fla. Dist. Ct. App. 1978).

65. *Id.* at 1275.

66. *Id.* at 1276-77.

67. See, e.g., *Texas Acorn v. Texas Area 5 Health Systems Agency, Inc.*, 559 F.2d 1019 (5th Cir. 1977); Vladeck, *Interest-Group Representation and the HSAs: Health Planning and Political Theory*, 67 AM. J. PUB. HEALTH 23 (1977).



for an effective CON process. In fact, the multiple levels of review required by the federal planning law may well have the effect of diminishing the quality and rigor of the final analysis.<sup>68</sup>

Finally, the increased functions of HSAs and state planning agencies required by the federal law will probably harm the process, rather than aid it, by significantly increasing the workload for CON reviews in a system that is generally unable to handle competently its current workload in an expeditious fashion.

If CON is to be an effective tool for cost-containment, additional changes to the CON mechanism must go beyond those presently embodied in P.L. 93-641 or now being considered as amendments. A reformed CON system must be capable of responding to the causes of health care inflation in a practical and effective fashion, recognizing the structural defects in the health care industry, the industry's political power, the American penchant for convenience and the latest in technology, and the currently prevailing mistrust of government and regulation. Without these basic reforms, the CON mechanism will have little, if any, impact on rising health costs.

#### *A. The Current CON Process Is Too Reactive*

Virtually by definition, CON is a passive and reactive mechanism. Under the current system, projects are conceived, developed and submitted by proponents who are under little, if any, obligation to confer with other interested parties—whether other institutional providers, cost-containment watchdog groups, public and private quality assurance agencies, third-party payors, or the CON review agencies. Because of the relatively short period of time (90 days)<sup>69</sup> generally allowed as the maximum for conducting all stages of a CON review (at the level of the sub-HSA, if any, HSA and state), once the project has been submitted and found to be “complete,” there is precious little time for other interested parties to mobilize—first, to decide whether to evaluate the project for its potential impact on their concerns or self-interest, then to conduct an adequate analysis of the proposal and, possibly, compare that study with any performed by other interested parties, and finally to submit the appraisal to the reviewing agencies at a point early enough in the review cycle to be useful. For projects commonly six months to two years in the making and hundreds of pages or more in

---

68. See text accompanying notes 165-79 *infra*.

69. 42 C.F.R. § 122.306 2(ii) (1977).

length, the fifteen to forty-five days generally available to carry out all these tasks is frequently inadequate, even if resources could be found to conduct such reviews.

This lack of sufficient time to respond is undoubtedly one reason for the predominance of "logrolling" among providers (the "I support your proposal, you support mine" syndrome) even when a specific project, if approved, could substantially injure the interests of a neighboring facility. The failure of providers to be actively involved in the review of applications from potential competitors denies the CON reviewers valuable information that may be available only from another health care provider in the community. It also tends to create a difficult political environment in which a project may receive wide ranging support far beyond its own intrinsic merit. The "batching" of several similar projects for CON review for the purpose of approving only one is now regarded as an important tactic for breaking up this "logrolling syndrome."<sup>70</sup>

Another problem resulting from the reactive nature of the CON process is that capital expenditures in the health field are initiated by health providers, who often respond to their own institutional imperatives rather than to the needs of the community they serve.<sup>71</sup> Consequently, CON review staffs spend much of their time on projects that are not developed to address the priority health needs of people in their service area—which should be the primary focus of their planning efforts. Had the resource development provisions of P.L. 93-641 (Title XVI), which were designed to replace the old Hill-Burton program, been funded by Congress, the reactive nature of the CON mechanism might have been lessened. While in most states CON may now represent the primary means of assuring public accountability of health care development, it is a negative control, not a positive one. A complementary affirmative planning mechanism is sorely needed.

#### *B. Few Incentives Exist to Support a Rigorous CON Decisionmaking System*

If CON decisionmaking were an exact science, the lack of incentives and support mechanisms for rigorous decisionmaking might be less important because CON decisions, however unpopular, could be objectively verified and thus shielded, at least to some degree, from the

---

70. See text accompanying notes 150-55 *infra*.

71. See, e.g., L. RUSSELL, TECHNOLOGY IN HOSPITALS 8 (1978).

pressures of influential groups. CON decisions, however, like many other public policy matters, are based on imperfect information, unproven hypotheses, and best guesses about outcomes. Consequently, they are subject to second-guessing and criticism—not all of which is constructive in either intention or effect.

CON decisionmakers presently have few incentives to say “no.” Second-guessing of CON decisions is commonplace, not only through the filing of administrative and judicial appeals, but through contacts with elected officials—both spontaneous and orchestrated—from an institution’s medical and administrative staff, its trustees, and the community it serves. Despite the popular rhetoric about consumer power, most consumers, no matter how much they may complain about rising health costs in the abstract, sympathize with the expansionist tendencies of their local hospital rather than with the cost-containment concerns of the CON reviewers.<sup>72</sup> Unless there is well-organized support from business or labor, as there has been in such cities as Detroit, Cincinnati and Rochester,<sup>73</sup> or a crisis involving the budget of a state because of accelerating Medicaid expenditures, as in New York and Massachusetts,<sup>74</sup> reviewers are loathe to deny CON applications in all but the most clear-cut cases. This reluctance exists at both the HSA level, where the activities of the chiefly private nonprofit agency require consensus, voluntary compliance, and support from the diverse provider community, and at the state level, where the threat of legislative or gubernatorial retaliation against the agency’s budget or personnel may arise when a politically unpopular CON decision receives attention.

Finally, given the passive and open-ended nature of CON and the self-doubt fostered by the use of imperfect data and imperfect evaluation tools in decisionmaking, there is little incentive for a reviewing agency to persevere and deny an application in the face of its own lingering uncertainty about the need for a project. These constraints become even more powerful when political pressures are delivered or anticipated from influential interest groups and when there is little opportunity for the CON reviewers to believe that the funds at issue—if denied in a particular case—would be redirected into a more appropriate health service project.<sup>75</sup>

---

72. LOUIS HARRIS POLL, *supra* note 11, at 56.

73. *See* note 111 *infra*.

74. *See* note 142 *infra*.

75. For an analysis of how a similar lack of incentives affects the operations of another health

*C. CON Programs Suffer from Lack of Accountability, Redundancy of Function, and Confusion over the Appropriate Role for Staff*

P.L. 93-641 has been applauded for its adherence to the principles of "bottom-up" planning. HSAs, unlike their predecessors, the CHP "b" agencies,<sup>76</sup> have the right to review CON projects and recommend approval or disapproval.<sup>77</sup> This language seems to contrast sharply with the "review and comment" responsibilities of the CHP "b" agencies.<sup>78</sup> In reality, however, HSA actions on CON applications may, depending on the provisions of the specific state law, be little more than advisory opinions for the state CON reviewing agency, which may conduct its own de novo review regarding the finding of facts and the application of law, health plans, standards and criteria relevant to the project.

In the case of a disagreement, the HSA has the right to receive from the state an explanation why its recommendation was not followed and to appeal from an adverse state action, assuming the agency possesses the financial resources to prosecute an appeal.<sup>79</sup> This is likely to be a rare event because most HSAs may well decide to spend their limited resources in other ways and would also be reluctant to antagonize the state health planning and development agency (SHPDA), an agency with which the HSA has repeated dealings, and with whom the HSA is likely to seek to remain on good terms.<sup>80</sup>

Sub-area councils, if they exist in a health service area, stand, for purposes of CON review, in the same relationship to the HSA as the HSA does to the SHPDA except that they lack any statutory basis and are without any appeal rights under P.L. 93-641. Nevertheless, in some jurisdictions they also conduct reviews of pending CON projects, fre-

---

regulatory agency, the PSRO, see Blumstein, *Inflation and Quality: The Case of PSROs*, in *HEALTH: A VICTIM OR A CAUSE OF INFLATION?* 245, 283-84 (M. Zubkoff ed. 1976).

76. Comprehensive Health Planning and Public Health Services Amendments of 1966, Pub. L. No. 89-749, 80 Stat. 1180 (codified in scattered sections of 42 U.S.C. (1976)).

77. National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, § 1513(f), 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300t (1976)).

78. Comprehensive Health Planning and Public Health Services Amendments of 1966, Pub. L. No. 89-749, 80 Stat. 1180 (codified in scattered sections of 42 U.S.C. (1976)).

79. 42 C.F.R. § 123.409(a)(9) (1977).

80. H. FOLEY, A REPORT ON THE CURRENT DEVELOPMENTS IN THE NATIONAL HEALTH PLANNING PROGRAM 14-15 (1978) ("The health planning act intended strong state and local participation in the planning process. We currently see a need for an even stronger role for the states.") (comments of Dr. Henry A. Foley, Administrator of the Health Resources Administration, to the National Council on Health Planning and Development).

quently holding hearings and rendering decisions based on their findings of fact and their applications of law, plans, standards and criteria. Their work, however, is only advisory to the HSA, whose decisions are, in turn, only advisory to the SHPDA.

Clearly, some economy must be brought to this system. If there were a single hearing before the final CON decisionmaker, lay reviewers could take their responsibility more seriously, the work of professional staff could be better focused and less overlapping, providers would complain less of redundant review procedures and their attendant costs, and interested parties, including community and consumer groups, could better concentrate their efforts. As the system is presently structured, concerned members of the public risk having their time and energies drained by the plethora of meetings, hearings and discussions now common to the CON system. Thus, the field is effectively left open only to the professional advocates and lobbyists whose job it is to attend all such meetings.

The present multiplicity of hearing levels also increases the possibility of inconsistency of findings among the reviewing agencies, especially since in most states no findings are binding upon subsequent reviewers until after the state level review. Even at the state level, appeals from the primary CON decisionmaker may, in some states, give rise to a full *de novo* review. Such inconsistencies may not only provide the basis for the filing of dilatory appeals, but also tend to undercut the apparent legitimacy of CON decisions; this is especially true of those CON actions that reject particular applications,<sup>81</sup> which under present state laws and judicial interpretations of standing constitute the great preponderance of CON appeals.<sup>82</sup>

Another problem with the current CON system is the lack of a clear control point. The SHPDA is responsible for the final administrative decision, but it possesses no direct administrative control over the HSAs or any sub-area councils. HSAs are funded directly by HEW; funds are not channeled through the state agency.<sup>83</sup> The concerns about HSA performance expressed by HEW have related primarily to grants management and requirements for HSA structure and procedures. Outcomes of performances have rarely been examined by

---

81. *See* *Northwest Hosp. v. Illinois Health Facilities Planning Bd.*, 59 Ill. App. 3d 221, 375 N.E.2d 1327 (1978).

82. *See generally* Dolan, *supra* note 32. Four states (Hawaii, Illinois, Minnesota and Washington) restrict appeals to denials only. *Id.* at 162 n.36.

83. 42 U.S.C. § 300f-5 (1976).

HEW in monitoring the activities of HSAs, especially in the regulatory review areas. In addition, HSAs are unable or unwilling to alter the performance of sub-area councils (where they exist), usually claiming that the tenets of P.L. 93-641 require, at least in theory, bottom-up planning.

The Statewide Health Coordinating Council (SHCC) is made up of between thirteen and eighty-three members. In most states, it meets several times a year, is composed of volunteer members, and is staffed by the SHPDA, though it usually also receives continuing input from HSA staff members (sixty percent of the SHCC membership is nominated by the HSAs).<sup>84</sup> This unwieldy structure and procedure makes it possible, even under the best of circumstances, for the SHCC to perform only its most fundamental assignments, such as providing advice to the SHPDA and making only the most general policy decisions. It is not an agency for resolving difficult questions regarding the operations of a regulatory system, such as the reasonableness of deadlines, the adequacy of review criteria, the quality of available health data, or the appropriate division of functions between competing state and regional bodies. In addition, HEW recently determined that the SHCC should not serve as the CON appeal body.<sup>85</sup>

This confusion over who is in charge makes it exceedingly difficult to manage, let alone reform, the system. The interested agencies themselves have no adequate place to resolve their differences, for even the state legislature lacks sufficient jurisdiction over the federally funded and federally accountable HSAs. The SHPDA that is nominally in charge of the CON program has no real control over the HSA, for it exercises no control over the HSA's budget, the hiring of its staff or the actions of its board of directors.

The absence of an administrative focus also makes it difficult for reformers outside the system, provider representatives or other government officials to fix responsibility for deficiencies in the program and initiate appropriate corrective measures when necessary. Of course, this lack of a locus for accountability can also feed the inherent bureaucratic tendency of CON agencies and HSAs to shift blame and deny responsibility for defects in the system.

Another troublesome aspect of CON programs is the uncertainty

---

84. See generally H. FOLEY, *supra* note 80, at 7, 15.

85. See Halpern, *The Statewide Health Coordinating Council: Can It Work?*, HEALTH L. PROJECT LIB. BULL., March 1979, at 99, 102.

over the appropriate role of CON review staff. Should staff be used strictly in evaluation or should it be engaged in negotiation with the applicant? If the latter, should negotiation take place concurrently with the evaluation, prior to it, or subsequent to it? Should staff be limited only to technical evaluation or should it, in the all too common case when there is no effective local constituency for cost-containment, also engage in soliciting support for staff findings emphasizing cost-containment from third party payors, large purchasers of health care, or consumer groups? These are certainly not easy issues, but they must be asked and answers must be sought—if only to generate a code of ethics for CON reviews that will help guide the reviewers and protect them from the collateral attacks of providers and consumers over their action or lack of action in bargaining for project alterations or in stimulating discussion and commentary regarding specific projects.

*D. Certificate of Need Lacks the Technical Tools Needed to Perform Effectively*

According to its sponsors, one of the primary advances of P.L. 93-641 over predecessor health planning programs was to be the increased emphasis on developing “state of the art” health plans of high quality.<sup>86</sup> The development of these plans would be made possible by providing the planners with the necessary resources, such as access to PSRO data sources. Adequate salaries would be paid to help the agencies recruit competent staff, including those with backgrounds in economic analysis, public administration and law; regional centers would be established to provide technical assistance to SHPDA and HSA staff and board members.<sup>87</sup> Federal guidance in plan development was to be provided through the promulgation of National Health Planning Guidelines and through closer federal supervision of local and state planning efforts.<sup>88</sup> Finally, by linking the quality of the agency’s plans to its prospects for survival (designation status, level of funding, etc.<sup>89</sup>), P.L. 93-641 sought to establish a strong incentive system for HSAs and SHPDAs to commit the necessary resources to perform satisfactorily in the plan development area. The intent was clear: plans were to be com-

---

86. See Zwick, *Initial Development of National Guidelines for Health Planning*, 93 PUB. HEALTH REP. 407, 408-10 (1978). But see text accompanying notes 67-68 *supra*.

87. See Klarman, *Health Planning: Progress, Prospects, and Issues*, 56 MILBANK MEM. FUND Q. 78 (1978).

88. See *id.*

89. See *id.*; Zwick, *supra* note 86.

prehensive and of high quality. Having been ratified by the public in an elaborate scheme of public hearings required under the law, they would provide a legitimate basis for the more controversial regulatory decisions that would follow—most notably those made by CON programs. In practice, however, health plans are unlikely to be timely enough, sufficiently comprehensive, or of high enough quality to be determinative in regulatory reviews. In some regions they may be useful, but they will not suffice as the sole or, in many instances, the predominant criteria for evaluating the merits of a proposed CON project. This is true for several reasons. P.L. 93-641 mandates a plethora of plans, but it does not require that a proposed CON project be included in any one of them as an absolute precondition to consideration. The initiative in the system still rests with the providers (the prospective applicants) rather than with the planners and CON reviewers. Hence, even in theory, P.L. 93-641 does not seek to impose a centralized planning structure on the health care sector.

The absence of centralized planning has significant implications for CON. Because projects submitted for CON review are of a wide variety and under the present law may be submitted at any time, effective plans must be comprehensive (that is, cover all possible CON applications including specific services and pieces of equipment) and must be continuously revised to remain current. Even the optimistic framers of P.L. 93-641 never intended a planning staff large enough to develop documents of sufficient breadth to cover all eventualities, nor did they anticipate that revision would be undertaken frequently enough so that all new developments in service delivery or equipment innovation could be covered.

It can be argued that in any market or mixed economy such as that of the American health care sector, plans may still serve useful social purposes even though they are passive and lack comprehensiveness. They can identify areas requiring attention, establish specific goals to address the problem areas, indicate strategies for goal attainment, and set standards to determine when the goals have been reached. No matter how useful these limited plans may be, however, they do not constitute a blueprint for CON decisionmaking as some supporters of P.L. 93-641 had hoped.

Of perhaps more immediate significance is the poor quality of the current set of health plans. The first generation of documents produced by the nation's HSAs—the Health Systems Plans (HSPs) and the An-



nual Implementation Plans (AIPs)—have been roundly criticized by their own sponsor, HEW, as well as by assorted consumer organizations. The plans have been characterized as long on description and short on analysis, advocating few, if any, prescriptions for useful initiatives, and possessing weak review criteria for purposes of such regulatory programs as appropriateness review, ratesetting and CON.<sup>90</sup>

Nearly four years into the implementation of P.L. 93-641—itself largely a continuation of the comprehensive health planning (CHP) program of seven years' duration<sup>91</sup>—it is difficult to believe that the planning efforts under P.L. 93-641 will show any sign of marked improvement in the near future. In fact, it is sadly characteristic of governmental planning programs in America—whether in health, social services or environmental matters—that document quality is almost uniformly poor.<sup>92</sup>

The reasons for the poor quality of the planning documents have yet to be carefully analyzed. It is clear that the state of the planning art is still primitive and that the concept of medical need has not yet been satisfactorily defined.<sup>93</sup> The inadequacies of health planning staff have long been suspected, although all available data indicate a relative improvement in education levels, experience and tenure of current personnel compared to those who had worked in CHP programs. Also cited have been the cumbersome multi-level board structures and procedures of P.L. 93-641, which lead to mediocre results when consensus-building efforts take priority over analytic rigor, an approach labelled in Colorado as the "least common denominator" method of planning. Instances of poor supervision of the planning effort by the federal government have also been admitted by federal spokesmen, including con-

---

90. An HEW Region VIII memorandum, April 20, 1977, found that "submitted HSPs and AIPs lacked the clarity and specificity to serve as the basis for the review decisions which a fully designated agency must make (e.g., Certificate of Need, Proposed Use of Federal Funds, etc.). In addition, the submitted plans failed to provide the level of specificity to serve as the foundation for the State Health Plan and The State Medical Facilities Plan."

91. Of 205 HSAs, 106 had been CHP "b" agencies. Implementation of National Health Planning & Resources Development Act of 1974, [1978] 3 MEDICARE & MEDICAID GUIDE (CCH) ¶ 29,405.

92. See generally Rein, *Social Planning: The Search for Legitimacy*, 35 J. AM. INST. PLANNERS 233 (1969).

93. For a description of the technical and conceptual problems inherent in a health plan development, see Bachman, *Health Planning—The Next Step*, 3 HEALTH L. PROJECT LIB. BULL., Dec. 1978, at 1. See also Medeiros, *supra* note 54, at 13-15; Somers & Somers, *supra* note 42, at 164; Wagner, *Criteria for Project Review*, 1 AM. J. HEALTH PLAN. 11 (1977).

tradictory directives, impractical work cycles, and overlapping plans.<sup>94</sup> Finally, as indicated above, there continues to be confusion over who is in charge of planning efforts within the state—the HSAs, the SHPDA, or the SHCC.<sup>95</sup>

Three additional deficiencies have greatly hampered effective planning and CON efforts. The first deficiency is the lack of a national technology assessment capability through which the efficacy and efficiency as well as safety of new medical technology can be tested and evaluated before proliferation. The second is the lack of quality of care data on a provider-specific basis. The third deficiency is the lack of population-based data, including utilization data.

In floor debate on the proposed 1978 amendments to P.L. 93-641, Senator Edward Kennedy estimated that the acquisition and utilization costs of new technology and equipment accounted for approximately fifty percent of the annual increase in hospital costs.<sup>96</sup> Despite the increasing importance during the past ten years of these “creeping intensity” factors for hospital inflation,<sup>97</sup> governmental scrutiny is only now beginning to include technology-related considerations that go beyond issues of safety (whether the device or procedure will do any harm) to address questions of effectiveness (will it do it faster and cheaper than what is already on the market) and efficacy (will it improve patient

---

94. There is some indication that in developing plans, the paper planning process sometimes takes over from the substance. And some HSAs submitted plans calling for what they knew we wanted. Much of this, I believe, has to do with our lack of a well thought out communications program from the Central Office through the Regions to the HSAs.

H. FOLEY, *supra* note 80, at 5. See also Zwick, *supra* note 86.

95. See, e.g., U.S. Comptroller General's Report to Congress on the Implementation of the National Health Planning and Resources Development Act of 1974. This report attributed the difficulties encountered by HSAs in developing plans to such problems as the “unavailability of health data and national standards and criteria for the health care system, inability to recruit staff, conflicts between local and state planning agencies over their respective responsibilities . . . , and delays in receiving technical assistance.” [1978] 3 MEDICARE & MEDICAID GUIDE (CCH) ¶ 29,405.

96. 124 CONG. REC. S11,905 (daily ed. July 27, 1978) (remarks of Sen. Kennedy).

97. In a December 1978 conference on medical technology sponsored by the Urban Institute in West Palm Beach, Florida, Dr. Hal Cohen, Executive Director of the Maryland Hospital Commission, cited a recent report by McKinsey and Company, Inc. that indicated that from 1974 to 1976 hospital cost per capita in the United States rose 7.9% faster than the cost of living. The McKinsey report broke down the 7.9% increase as follows: 1.6% for hospital wage increases above cost of living; 1.7% for more labor per “patient day equivalent”—a measure that includes a weighting for outpatient activity; 4.4% for real non-labor cost increase per patient day equivalent; and 0.1% for more patient day equivalents per capita. The report identified the components of the 4.4% increase as constituting supplies and equipment associated with doing more tests and other ancillary activities per patient day—what Cohen labelled “Creeping Intensity.” H. Cohen, Information Needs in the Public Sector 9 (December 1978) (copy on file in the office of the North Carolina Law Review).

outcomes).<sup>98</sup> Concurrently, the subject matter focus is also beginning to reach beyond pharmaceuticals to small medical devices<sup>99</sup> and, more recently, to larger institutional-based medical equipment like CAT scanners<sup>100</sup> and procedures like fetal monitoring.<sup>101</sup>

The lack of facility-specific quality of care data has been very damaging. Without this information, health planners and CON reviewers can, in the midst of the current anti-inflationary campaign, be accused of engaging in blind budget-cutting without regard to quality or, alternately, of simplistic, rigid planning evidenced by a mechanistic application of formulas (for example, "X" number of open-heart surgical procedures per year equals good care). If they are sensitive to such charges, CON reviewers and planners may, in some cases, overcompensate and misinterpret the nature of a project, in the mistaken belief that quality of care considerations, rather than the imperatives of institutional economics (such as providing a profitable service like alcoholism treatment) or of institutional politics (such as accommodating the medical staff's desires for convenience or the latest technology), are prompting the submission.<sup>102</sup>

Furthermore, the lack of quality of care data can place CON reviewers in a difficult position when reviewing innovative projects that, if approved, would inject a competitive alternative—a real freedom of choice—into the health care system of a community. Such projects are frequently resented by the established health care providers of the community, and quality of care is customarily the reason given publicly to justify this opposition. Now that anticompetitive practices of profes-

---

98. See generally A. COCHRANE, *EFFECTIVENESS AND EFFICIENCY* (1972).

99. See generally Iglehart, *supra* note 12.

100. See OFFICE OF TECHNOLOGY ASSESSMENT, *POLICY IMPLICATIONS OF THE COMPUTED TOMOGRAPHY (CT) SCANNER* (1978).

101. See H. BANTA & S. THACKER, *THE PREMATURE DELIVERY OF MEDICAL TECHNOLOGY: A CASE REPORT* (1978), in which the authors assert that the uncertain benefits of electronic fetal monitoring, and its associated costs (more than \$300 million annually) and risks (including a likely increase of 100,000 Caesarian sections per year with accompanying risks to the mother of death and pelvic infections) do not seem to justify the technique's widespread use.

102. For a recent study indicating that adoption of technology often appears unrelated to medical need, see L. RUSSELL, *supra* note 71, at 173, 175-76 in which the author observed that adoption of cobalt therapy, electroencephalography, open-heart surgery and renal dialysis occurred faster in areas in which the level of insurance coverage was higher and proceeded more rapidly as that level grew. Further, she found that these technologies were more likely to be adopted in such areas than in those areas with a higher incidence of related diseases. See also J. CROMWELL, P. GINSBERG, D. HAMILTON & M. SUMMER, *INCENTIVES AND DECISIONS UNDERLYING HOSPITALS' ADOPTION OF MAJOR CAPITAL EQUIPMENT* (1975).

sional trade associations are coming under increasing scrutiny,<sup>103</sup> tactics such as the denial of hospital staff privileges to physicians affiliated with an alternative delivery system are no longer available. Participating in the CON process may become a legally sanctioned substitute tactic. This is true in Colorado, where, despite the general reluctance of providers to contribute to the public debate over specific CON projects, providers often break their silence when an innovative project is submitted for CON review.

One Colorado example is especially noteworthy because a pivotal issue in the deliberation—and the issue seized upon by the local physicians—was the quality of care offered by the applicant. The project being proposed was a for-profit ophthalmologic clinic that would perform certain kinds of cataract surgery on an out-patient basis in competition with the local hospital. The owner of the clinic was also the surgeon who would be performing the operations. Despite the doctor's international recognition for his pioneering work in ophthalmological surgery and his years of practice at the local hospital without any apparent problems, allegations were made, without further documentation, that the clinic might provide an inferior quality of care. In the absence of data, allegations were traded between the proponents of the clinic and those of the hospital. Notwithstanding a positive recommendation by the HSA's staff, the HSA voted to recommend denial of the project. Then, after lengthy debate at the state level, the HSA recommendation was rejected and the CON was granted.

The unavailability of data on the quality of care issue in that case was of crucial importance. Had it been available, it could have been used to compare the performance of the would-be clinic owner with that of his former colleagues at the hospital and his peers elsewhere in Colorado (if not the nation), and it could have been used to evaluate the performance of comparable clinics elsewhere in the nation vis-à-vis the care being rendered in hospital settings for the same type of patient and care. Some of the data in question—at least the portion pertaining to the hospital-based activities—had already been collected by the local PSRO. Because of current federal policy, however, that data was not available to the CON decisionmakers,<sup>104</sup> and comparable data is not

---

103. See Iglehart, *supra* note 19. See also Havighurst, *Professional Restraints on Innovation in Health Care Financing*, 1978 DUKE L.J. 303.

104. HEW Proposed Rule on Confidentiality and Disclosure of Professional Standards Review Organization (PSRO) Information, 44 Fed. Reg. 3058 (1979). *But see* Public Citizen Health Research Group v. Department of Health, Education and Welfare, [1978 Transfer Binder] MEDI-

collected or available through other sources.

Making decisions in such cases without adequate data is not only difficult and potentially risky for the decisionmaker, but it is, simply speaking, bad decisionmaking. Obviously, rational decisions require information, especially when the decisionmaking process becomes subject to increasing political pressures as is now occurring in the health care industry. That some of the information necessary for a viable CON program has already been collected means that the task is less monumental than some believe. The data, however, must be made available or else the public will be forced to assume the cost of a duplicative collection effort.<sup>105</sup>

The lack of good demographic data is also of critical importance because sound population estimates and projections, including those relating to rate of growth, and a population's anticipated racial, age and socio-economic characteristics and its rates of mortality and morbidity, have great import for future planning decisions. Given the dynamic nature of community populations and the rapid change in health delivery systems, health planning cannot be based on a static model.<sup>106</sup> Absent definitive population projections, poor decisions will be made, and they will be subject to well-deserved criticisms. Finally, population-based utilization rates can be far more instructive regarding problems in the delivery system than facility-based rates. Epidemiological studies of health services utilization is a critical tool for an intelligent health planning and regulatory system. Results from these studies can indicate excessive utilization and surplus resources in com-

---

CARE & MEDICAID GUIDE (CCH) ¶ 28,943 (D.D.C. Apr. 25, 1978), in which Judge Gesell of the United States District Court for the District of Columbia ruled that PSROs were "public agencies" within the meaning of the federal Freedom of Information Act (FOIA) and therefore were required to release information to the public if so requested unless they could qualify for the limited exclusions under FOIA for specific types of information on the basis, for example, of confidentiality. The case is now on appeal.

105. See, e.g., National Governors' Association, *The Report of the Committee on Health Information for Policy Development* (1978). The Committee identified two basic categories of health information systems: "[i]ndividual systems developed primarily for the purpose of monitoring compliance with governmental programs," and "[d]ata systems developed, irrespective of compliance issues, for long-term planning and decisionmaking. Some of the major problems concerning health data systems seem to arise from the fact that the two systems are rarely integrated." *Id.* at 3. The report noted that great quantities of data are being collected at a substantial expense (between \$60 and \$80 million annually for HEW alone) and that "all too often these data are not translated into information [usable for program purposes] and not passed on to governmental or private decisionmakers in a timely fashion." *Id.* at 4. The Committee recommends a national health information system with ready access by both public and private users, and makes specific proposals regarding the components of the system, the flow of data, and the accuracy, accessibility and timeliness of data.

106. B. ABEL-SMITH, *VALUE FOR MONEY IN HEALTH SERVICES* 173 (1976).

munities that, at first appearance, might seem to have appropriate occupancy rates and lengths of stay in their facilities. Moreover, population-based reviews are also indispensable in identifying real public health problems.<sup>107</sup>

### *E. CON Lacks Quality Control Mechanisms*

At the present time, compliance with CON requirements, including submitting a project for review and complying with representations made on the application forms after the CON has been awarded, is neither monitored nor enforced. Perhaps for the great majority of providers this is unnecessary; voluntary compliance by a majority with the chief provisions of a regulatory scheme is always a precondition to the success of a regulatory program. But there are undoubtedly some providers who would not feel compelled to comply with requirements they find burdensome and useless. Furthermore, should CON reviews become more stringent, with chances for success consequently becoming less certain and the cost for preparing and presenting a CON application increasing, total reliance on an honor system may become a somewhat naive way to assure compliance with the terms of a review process that involves such vast sums.<sup>108</sup> The tight-lipped provider community, behaving much like the proverbial physicians in the operating room with their "conspiracy of silence," will rarely inform on one another. At the present time, provider gossip is the sole source of information to the CON agency about "end runs," since there is no audit of providers that would detect such evasive efforts, even under the cost determinations of Medicare, Medicaid or private insurers. Thus, there is no way to estimate the extent of this problem.

If a CON application is submitted and rejected, assuring compliance with the negative decision is also a matter of some concern. It is, however, the one aspect of this area that has received attention. HEW is now requiring states, as a precondition for full SHPDA designation

---

107. For instance, when a community is identified with a utilization rate for chest-related ailments markedly higher than for other communities with similar demographic characteristics, an investigation would examine the reasons for the disparity, including the possibility that the higher utilizing community suffers from an infectious, hereditary or environmentally related disease. See Wennberg & Gittelsohn, *supra* note 23. See also J. ROBBINS, *THE USES OF POPULATION-BASED DATA FOR RATE SETTING* (1976).

108. If the CON review process were administered in every state pursuant to federal requirements, it would have reviewed projects during 1978 totalling \$6.8 billion. *Hospital Cost Containment Act of 1977: Hearings on S. 1391 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 1st Sess. 839, 891 (1977)* (statement of Alice M. Rivlin, Director, Congressional Budget Office) [hereinafter cited as *1977 Hearings*].

under P.L. 93-641, to possess adequate sanctions to enforce negative CON decisions,<sup>109</sup> and third-party payors, most notably several Blue Cross plans,<sup>110</sup> have assisted CON reviewers in enforcing their decisions.

Once a CON has been granted, there is little continued monitoring to see if the applicant has complied with the terms of the CON project application. Frequently, the basis for a decision granting or denying a CON can be found in the specific assurances made in the application—for example, that the equipment will be purchased at a given price, that the charge for the service will be lower than that prevailing in the community, or that outreach efforts will be made to medically underserved areas. At present, however, little is done to ensure that these conditions are ultimately met. Even reports of cost overruns, for which many CON statutes require a subsequent approval, are now submitted chiefly on a voluntary basis and, at least in Colorado, are submitted more frequently by the smaller, rural facilities, which are not the primary target of the CON cost-containment, than by the large urban facilities with advanced accounting systems.

#### IV. PROPOSALS FOR REFORM

CON programs must be overhauled if they are to attain the stated purpose of helping to make the American health care system more effective, efficient and equitable. Experience indicates that, without extensive changes, the successes of the CON program will be few and far between and will be largely attributable to circumstances in which there is a dedicated agency, a substantial data base, an established tradition of intervention in the health delivery system, and a politically supportive environment—a cluster of factors neither present generally in the nation at this time nor likely to occur in the foreseeable future.<sup>111</sup>

---

109. 42 C.F.R. § 123.405 (1977).

110. Blue Cross plans in Kansas City and Cincinnati have been especially active in this assistance. Over 20 plans have provisions in their reimbursement contracts with participating hospitals stating that the plan will not cover the costs of a project that has failed to receive planning agency approval. For a more detailed description of the aggressive steps taken by Blue Cross of Kansas City to reduce a controversial proposal from 120 new acute care beds to 40 in an area where there already was a documented excess of beds, see BLUE CROSS-BLUE SHIELD ASSOCIATIONS, *THE BLUE CROSS AND BLUE SHIELD CONSUMERS EXCHANGE* (1978). For an evaluation suggesting that Blue Cross plans may increasingly act in pro-consumer fashion in the future, see Schonbrun, *The Future of Blue Cross*, 2 J. HEALTH POL., POL'Y & L. 319 (1977).

111. Singled out for special attention have been such areas as Rochester, New York, where Kodak, Xerox and the University of Rochester have historically joined forces with elements of the consumer and provider community. Detroit (with the "big three" auto makers, the United Auto Workers, the University of Michigan and a traditionally progressive state government), Cincinnati

Consequently, what is needed are solutions tailored to the more typical circumstances that now confront most CON agencies. The strategies must seek to impose efficiency, economy, quality control and accountability on the CON system, and, whenever possible, they should be self-enforcing. Existing competitive pressures among providers should be relied upon whenever appropriate. Approaches designed to raise the public consciousness about costs should be sought. At the same time, proposed solutions should aim to provide the CON programs with sufficient political support and with appropriate incentives to carry out their responsibilities with vigor even in the face of advancing technology, the continuing political power of those supporting the status quo, the present lack of data, and the questionable quality of existing health service plans and review criteria.

With these objectives in mind, the remainder of this article will outline several proposals for reforming the CON system. First, a series of general reforms will be discussed, and then the following specific proposals will be examined in greater detail: (1) imposing on states an annual lid on new health-related capital expenditures; (2) requiring that a project first be cited in the facility's long-range plan before it can be considered for a CON; (3) providing for partial and conditional approvals; (4) applying the doctrine of *res judicata* to projects that are similar to proposals already rejected and the doctrine of the "substantial evidence" rule to CON appeals; and (5) imposing time-limited and/or site-limited moratoria on projects based on new medical technologies.

#### *A. Streamlining the Process: General Suggestions for Reform*

As in other license and permit procedures, the burden of proof in the CON process should be on the applicant. Yet, many current state statutes are vague or ambiguous on this point. In practice, it is frequently the CON decisionmaker who carries the true burden of showing that a proposed project should be rejected because it will not meet a community need as expressed by existing plans and criteria. The provisions of P.L. 93-641 help address this ambiguity, at least for new hospi-

---

(with an especially progressive Blue Cross plan, Proctor & Gamble and progressive city leadership), and Phoenix (with Motorola and a well-respected, long-tenured HSA director) have also been named. They are the exceptions that prove the rule, for there are few structural similarities among these cities, much less anything that could be readily transferred to other parts of the country.



tal in-patient services,<sup>112</sup> by requiring that the CON decisionmaker affirmatively make a series of findings regarding need. Despite this improvement, the issue of burden of proof is still unclear and should be resolved. Rigor in applying an appropriate burden of proof will not only aid the efforts of the CON review agency, but also may change the applicant's behavior and subsequently its willingness to consider, when necessary, appropriate alterations to an already submitted application.

Information is an indispensable tool for adequate planning and regulation. Data that is both demographic-based and facility-specific (especially regarding quality of care costs) can be obtained through an improved data collection and dissemination effort. Much data is already available and in the possession of such quasi-public agencies as PSROs and the Joint Commission on Accreditation of Hospitals (JCAH), as well as state and federal Medicaid and Medicare agencies, but has not been aggregated or released to health planning or CON programs.<sup>113</sup>

A code of ethics must be established for CON reviewers, both to guide their efforts and to shield them from inappropriate political pressures.

In the interest of improving the system's accountability, reducing the costs (both economic and social) of compliance, and making its decisions more consistent and more rigorous, there should be a unified CON administrative review process and a single definitive CON decisionmaker. Under such a system, responsibility for breakdowns could be clearly assigned, and interested parties, such as concerned consumer groups and other providers, could concentrate their efforts on a single proceeding. Applicants could focus their efforts toward satisfying the concerns of only one decisionmaker, thus eliminating the "whipsaw" effects that may now occur in the present system—either of the applicant by the HSA and the state agency (for example, the reviewing agencies making incompatible demands of the applicant) or of the reviewing agencies by the applicant (for example, the proponent playing off one agency against the other).

Furthermore, this unified CON review process should be a state operated system.<sup>114</sup> Despite the role played by the federal government

---

112. 42 C.F.R. § 123.410 (1977).

113. See notes 104 & 105 *supra*.

114. For a review of the increasing federal support for the concept of a larger voice for states in health policy formation and administration, see Iglehart *Carving Out a Role for States in Con-*

in establishing CON programs, they are basically state administered. Legal assistance, increasingly necessary as the CON and health planning system grows more litigious, is provided through each state attorney general's office.<sup>115</sup> The governor, with power over the tenure of ranking agency officials, and the state legislature, with control over funding appropriations for the program, can effectively monitor and, when necessary, correct abuses in the operations of the CON programs. Coordination with other related regulatory reviews, including facility licensure and hospital rate review (in those states where it exists), can only be effected at the state level.<sup>116</sup>

Giving the HSAs or other quasi-public bodies the power to make final CON decisions would create several problems. Because HSAs are generally sub-state entities, problems regarding intrastate consistency would be likely—a potentially troublesome occurrence, particularly since states continue to be the most frequently used political boundaries for health decisionmaking and data collection.<sup>117</sup> Most HSAs operate without specific state enabling legislation, and many continue to suffer from inadequate consumer involvement and, consequently, insufficient political accountability.<sup>118</sup> In many states, such as New York, their relationship to other ongoing state regulatory review programs has reportedly been one of competition and/or avoidance. The HSA's

---

*trolling Hospital Costs*, 10 NAT'L J. 1045 (1978). See also Somers & Somers, *supra* note 24, at 154-55 for support for the idea that the state should play the dominant role in CON.

115. The comments of an attorney who represents several California HSAs are illustrative:

From the HSAs' perspective, perhaps the key issue is one of too many lawyers or, to put the matter more accurately, the issue is the gross disparity between the vast amount of legal resources available, on the one hand, to the health industry and the relatively small amount of legal time available to the HSAs, on the other. . . . As part of the [hospital] industry strategy, any planning activity perceived as an undesired constraint on expansion of the industry is translated into an issue to be resolved in a legal forum such as a court or the legislature. Virtually all effective acts on the part of health planners are so perceived. In short, the health planning process has been so legalized that agencies without legal resources have little, if any, role in the final decision-making process. . . . [H]ealth planners, because they have lost almost all their legal battles, have been intimidated in their pursuit of planning options, and the HSAs in this state at least have become growingly isolated from any significant role in CON determinations.

S. Price, *Health Planning and the Law 7-9* (speech delivered at the National Health Lawyers' Association Conference, October 27, 1978).

116. See generally MILLER & BRYNE, INC. & JPB ASSOCIATES, INC., FINAL REPORT: EVALUATION OF THE IMPACT OF PHS PROGRAMS ON STATE HEALTH GOALS AND ACTIVITIES (Health Resources Administration, Washington, D.C. 1977); Altman, *The Politics of Health Care Regulation: The Case of the National Health Planning and Resources Development Act*, 2 J. HEALTH POL., POL'Y & L. 560 (1978).

117. National Governors' Conference Center for Policy Research Analysis, *Making the National Health Planning Law Work: The State Perspective* (1977).

118. See, e.g., *Texas Acorn v. Texas Area 5 Health Systems Agency, Inc.*, 559 F.2d 1019 (5th Cir. 1977).

“voluntary” approach to problem solving based on a consensus model of decisionmaking and its proximity to “grassroots” concerns of access rather than systemic cost-containment make rigorous CON decision-making exceedingly difficult.<sup>119</sup> At present there are no comprehensive comparisons of the CON performance by HSAs vis-à-vis that of state agencies,<sup>120</sup> but in Colorado, at least, CON reviews performed by HSAs have tended to be less rigorous and less sensitive to cost-containment concerns than those conducted by the state.<sup>121</sup>

The HSAs, however, could play a productive role under a unified system that would be very appropriate for these regional planning bodies. Specifically, the HSAs could provide more technical assistance to applicants, stimulate new CON applications to address current community needs, and serve as an “honest broker” between the applicant and the state CON review agency. The HSAs could also monitor the conformity of CON decisions with the various plans being generated under the provisions of P.L. 93-641—plans that HSAs play a dominant role in formulating. Under the present system, with its redundancy of functions, neither the SHPDA nor the HSA has had the staff or the time necessary to perform any of these important tasks adequately.

Finally, HSAs could serve as a “backstop” for the CON system. In instances such as that in Ohio when the state CON review agency fails to carry out its duties in a responsible way,<sup>122</sup> the HSAs within a state could—singly or collectively—be authorized by HEW to take over the role as the CON decisionmaker for the state.

Plans and criteria should be formally promulgated as regulations under the state’s APA before they are relied upon by the CON decisionmaker. A federal court in Nebraska recently reversed a negative decision rendered by the state CON decisionmaker because it failed to

---

119. See generally A. Wildavsky, *Can Health Be Planned?* (1976 Davis Lecture, University of Chicago Graduate School of Business).

120. The survey now being conducted by the American Health Planning Association may provide the base data for such a comparison. See note 37 *supra*.

121. See, e.g., Colorado Dep’t of Health, *Annual Report of the Health Facilities Advisory Council* (1978). See also Altman, *supra* note 116, at 572-73 (citing seven recent reversals in a six month period of HSA decisions by the state CON decisionmaker in Massachusetts).

122. See H. Foley, *Report of the Health Resources Administrator* (HEW, Washington, D.C. 1978). The report notes that the Administrator of HRA threatened the state CON agency, the Ohio Department of Health, with loss of its SHPDA designation and potentially other HEW funding if it did not improve its CON performance. The Ohio agency had overturned, without explanation, two negative HSA recommendations on multi-million dollar hospital expansion projects in Cincinnati and Dayton.

have its criteria properly adopted.<sup>123</sup> The court made this ruling even though the state agency was operating only under the authority of the 1122 program,<sup>124</sup> whereby it rendered not a final decision but only a recommendation to HEW, and even though the 1122 statute and regulations themselves contain criteria of much detail and specificity, which would tend to obviate the need for further rulemaking. In New Jersey, where the courts have granted state authorities considerable latitude in conducting the CON program, rulemaking has also been widely regarded as a basic precondition for a legally sound CON system.<sup>125</sup>

Finally, proponents of a strong CON system will find that they can bolster their authority over the health system through rulemaking efforts. Courts are more inclined to defer to the expertise of administrative agencies and to allow those agencies broader discretion when they engage in actions that have a general effect and are only prospective in nature (rulemaking) than when they engage in actions that affect the rights of specific parties and are retrospective in nature (adjudications).<sup>126</sup>

### *B. Living Within a Budget: Setting an Annual Lid on Capital Expenditures*

During the past two years increasing attention has been paid to the concept of capping the nation's health expenditures.<sup>127</sup> In Rhode Is-

123. *Nebraska Methodist Hosp. v. Casari*, [1978 Transfer Binder] *MEDICARE & MEDICAID GUIDE (CCH)* ¶ 29,205 (D. Neb. Aug. 18, 1978).

124. *Id.*

125. *See generally* *Cooper River Convalescent Center, Inc. v. Dougherty*, 133 N.J. Super. 226, 336 A.2d 35 (1975) (upholding legality of 18-month moratorium on construction of intermediate care facilities promulgated as regulation by regular body of state government, the Health Care Administration Board).

126. *See generally* *Northwest Hosp. v. Illinois Health Facilities Planning Bd.*, 59 Ill. App. 3d 221, 375 N.E.2d 1327 (1978). The court observed that the standard for reviewing the determinations of an administrative agency varies with the nature of the action taken:

"When an administrative agency exercises its rulemaking powers, it is performing a quasi-legislative (as opposed to a quasi-judicial) function. This fundamental principle explains the discrepancy in the standards of judicial review of each type of proceeding; that is, when dealing with an adjudicatory proceeding, a reviewing court may only set aside the agency decision if it is clearly against the manifest weight of the evidence. When reviewing administrative rules and regulations, on the other hand, a court may not invalidate the regulation unless it is clearly arbitrary, unreasonable or capricious, because administrative agencies are inherently more qualified to decide technical problems and the mechanics of dealing with them. Because the courts lack the expertise possessed by administrative agencies, they should hesitate to find a regulation unreasonable."

*Id.* at 226-27, 375 N.E.2d at 1331-32 (quoting *Shell Oil Co. v. Pollution Control Bd.*, 37 Ill. App. 3d 264, 270-71, 346 N.E.2d 212, 218 (1976)).

127. *See, e.g.*, 125 CONG. REC. S2216 (daily ed. March 7, 1979) (remarks of Sen. Javitts).

land a consortium of public and private agencies sought to impose a "maxicap" on total expenditures in all hospitals of the state.<sup>128</sup> A similar voluntary effort is now underway in Rochester, New York.<sup>129</sup> In the Hospital Cost Containment Bill of 1978, President Carter proposed that limits on expenditures be imposed in two distinct areas of rising costs: capital expenditures were to be limited to \$2.5 billion annually, with allocations assigned to each state based on population, while increases in a facility's operating costs were to be kept, subject to tightly drawn exceptions, within a 9% cap.<sup>130</sup> In 1979 a new federal cost containment bill was introduced, designed to set the lid on capital expenditures at \$3 billion and on operating expenses at 9.7 percent.<sup>131</sup> New York has been contemplating a lid on new capital expenditures alone, believing it too difficult, both technically and politically, to impose a cap on operating costs.<sup>132</sup>

The implications for CON reviews of imposing a capital expenditure limit are significant. By establishing an overall budget for capital expenditures, several positive effects should result. First, the substantial capital expenditures and operating costs that accompany new projects would be significantly curtailed. The \$2.5 billion lid originally proposed by President Carter was estimated to be approximately fifty percent of the total spent the previous year on capital expenditures.<sup>133</sup> Additional savings in operating costs would also be substantial inasmuch as it has been estimated that the annual operating costs that accompany a new capital expenditure range between twenty and one hundred percent of the total cost of the capital expenditure itself.<sup>134</sup>

Second, by setting the lid at a specific figure that is high enough to be responsive to demonstrated needs yet low enough to result in cost savings, the concept of "relative need" can be introduced into the CON

---

128. See generally Zimmerman, Buechner & Thornberry, *Prospective Reimbursement in Rhode Island: Additional Perspectives*, 14 INQUIRY 3 (1977).

129. Sorenson & Seward, *An Alternate Approach to Hospital Cost Control: The Rochester Project*, 93 PUB. HEALTH REP. 311 (1978).

130. Several bills were introduced during the 1978 congressional session. The most prominent were S. 1391, introduced by Sen. Edward Kennedy (D. Mass.), and H.R. 9717 and H.R. 5285, introduced by Rep. Paul Rogers (D. Florida). See generally HEALTH CARE FINANCING ADMINISTRATION, DEP'T OF HEALTH, EDUCATION AND WELFARE, HOSPITAL COST CONTAINMENT: A SUMMARY OF LEGISLATION PENDING BEFORE THE SENATE OF THE UNITED STATES (1978).

131. 125 CONG. REC. S2207 (daily ed. March 7, 1979).

132. See generally NEW YORK STATE OFFICE OF HEALTH SYSTEMS MANAGEMENT & NEW YORK STATE HEALTH PLANNING COMMISSION, BRIEFING BOOK: THE CAPITAL EXPENDITURE LIMIT PROGRAM (1978) [hereinafter cited as NEW YORK STATE BRIEFING BOOK].

133. See 1977 Hearings, *supra* note 108, at 892.

134. See Somers & Somers, *supra* note 24, at 153-54.

review system.<sup>135</sup> This concept brings an element of discipline into the health care system by forcing CON reviewers to recognize that while virtually any project may be found to benefit some people,<sup>136</sup> some projects will prove more beneficial to the population at large, and because of the growing constraint on resources should be given priority. For example, a project that provides primary care services to a medically underserved population such as migrant workers or inner-city families should be granted a higher priority<sup>137</sup> than a tertiary care project involving a new piece of medical equipment of untested efficiency, effectiveness or safety capable of serving relatively few patients and yielding no meaningful research findings.<sup>138</sup>

Under this system, the inclination of CON reviewers to say yes to a project of limited or unknown value would decrease,<sup>139</sup> for several reasons. With a limited budget, approving a marginal project may force CON reviewers to disapprove a more deserving project later in the year; consequently, proponents of projects (especially those submitted early in the year) will have to meet their burden of proof. Providers themselves may find it necessary to testify against projects of other providers to preserve funds in the system for their own projects. This would help to generate a favorable political environment for CON reviewers that would be more conducive to saying no than the present one marked by its "logrolling" efforts.<sup>140</sup> This environment might also help produce useful critiques of projects that often can be prepared only by another facility. What the market has failed to produce and what the antitrust laws have, to date, failed to remedy may instead be fostered by an annual cap on CON expenditures.

Furthermore, under such competitive circumstances, a full reli-

---

135. See NEW YORK STATE BRIEFING BOOK, *supra* note 132, at 5-11.

136. In some instances, as with convenience items for physicians, the benefit may fall primarily on the providers themselves.

137. "Over a third of America's children, especially those who are poor or are members of minority groups, are not immunized against childhood diseases; thus, epidemics of diphtheria and measles still occur with unpleasant frequency." Silver, *Health Services for Children*, YALE ALUMNI MAGAZINE & J., February 1979, at 14.

138. See generally A. COCHRANE, *supra* note 98. Cochrane notes the need to conduct rigorous effectiveness trials on new methodologies for the delivery of care before introduction to the general market. The treatment of research oriented projects received little attention in the congressional hearings held prior to the passage of Pub. L. No. 93-641.

139. See, e.g., H. Cohen, *New Principles of Reimbursement for Capital Costs, Geared to HSA and SHPDA Plans*, in LINKING HEALTH PLANNING AND REGULATION TO INCREASE COST EFFECTIVENESS, *supra* note 54, at 8-12; NEW YORK STATE BRIEFING BOOK, *supra* note 132, at 11.

140. See generally Nelson & Winter, *In Search of a Useful Theory of Innovation*, 6 RESEARCH POL'Y 36 (1977).

ance on health plans for CON decisionmaking would be less necessary because a more complete record would be developed based on the informed comments provided by rival institutions.<sup>141</sup> Substantive comments from competing providers would supplement the established plans and criteria if they were comprehensive and of good quality or help supplant them if they were overly narrow, biased or of poor quality. This feedback would also be useful in examining the quality of prepared plans and criteria indicating areas requiring revision or wholesale change.

If a federal cost containment bill were enacted, an annual lid of \$2.5 or \$3 billion would be instituted for all proposed capital expenditures nationwide. Allocations of the total amount would be made on a state-by-state basis according to population. Further allocations could be made by state officials according to health service area or other sub-state geographical unit. State CON reviewers would presumably administer the capital expenditure lid. Such an arrangement might have considerable utility. The state officials, midway between the pressures of local communities and local providers on one hand and the federal government on the other, could make tough but still well-informed decisions. The state CON program could benefit from having to operate within a budgeting constraint, but its officials would not have to take the political heat for its existence or its level. Even if the CON program were to become an increasingly state-operated program as recommended above, cost-containment considerations would be accorded great weight, if for no other reason than the financial pressures that rising Medicaid and health insurance coverage costs for the large work force of state employees continue to place on state budgets and consequently on state taxes.<sup>142</sup>

---

141. See, e.g., *Olathe Hosp. Foundation v. Extencicare, Inc.*, 217 Kan. 546, 539 P.2d 1 (1975). In *Olathe*, two nonprofit hospitals challenged a CON proposal by a for-profit hospital chain to establish a new 400 bed facility almost midway between them. Several recent cases in New Jersey, where batching of applications is an established practice, are also of interest. See, e.g., *National Nephrology Foundation v. Dougherty*, 138 N.J. Super. 470, 351 A.2d 392 (1976) (one CON awarded to establish an intermediate renal dialysis facility although three applications reviewed concurrently). See also *Saint Joseph's Hosp. v. Finley*, 153 N.J. Super. 214, 379 A.2d 467 (1977), cert. denied, 75 N.J. 595, 384 A.2d 825 (1978). In *Saint Joseph's*, a CON for a cardiac surgery program was denied on the ground that only two of nine facilities presently offering the service in the region met a minimum standard utilized by the CON decisionmaker. Although the cardiac surgery standard used had not been promulgated as a regulation, the court found that sufficient credible evidence existed in the record. *Id.* at 222, 379 A.2d at 470. The court's opinion is silent on the role played by the nine other facilities, but it is clear that information on the utilization of the other hospitals' services—whether volunteered by the other facilities or solicited by the reviewers—played a critical role in establishing the necessary credible evidence.

142. In Massachusetts, for example, a \$90 million increase in Medicaid expenditures between

Several states may not wait for federal action. Officials in New York and Maryland have capital expenditure programs under active consideration.<sup>143</sup> Like the pending federal legislation, the state programs would establish relative need as the context for all CON decisions and would consequently affect the behavior of CON reviewers, providers and other interested parties. A lid thus enacted at the state level might have greater perceived legitimacy to the general public and the provider community than one passed in Washington. Greater sensitivity to unique local conditions, such as the rapid population growth in parts of the West and South requiring new construction projects or the aging physical plants of established medical centers in the urban Northeast requiring extensive renovation work to meet building and fire code requirements, might also make the lid established for a state or sub-state region more appropriate than one based strictly on present state population figures. Nonetheless, a federal overview of state established capital expenditure limits might be necessary and appropriate if only to assure that the total sum of the state lids did not exceed an acceptable national level.

Determining the actual level of the lid will necessarily involve an element of arbitrariness and negotiation, not only because the human need for health care and its desired and presumed end-product—good health—is difficult to value,<sup>144</sup> but also because the tools to evaluate the impact of capital expenditures on total actual health expenditures are currently very imprecise. If the nation decided that it wanted to place a

lid on capital expenditures in the health care sector<sup>145</sup> (as in Maryland, for example, for national purposes), and to appropriate to research and development a fixed percentage of total health care expenditures, one percent for research,<sup>146</sup> one percent for

7 and 1978, from \$630 million to \$720 million, represented more than one-half of an increase in the state budget during that period, with 73% of these expenditures hospital and nursing homes, the target of CON and other P.L. 93-641 functions. note 116, at 569-70.

g., H. Cohen, *supra* note 139; NEW YORK STATE BRIEFING BOOK, *supra* note 132.

generally Knowles, *The Responsibility of the Individual*, 106 DAEDALUS 57 (Winter 1977); M. LALONDE, *A NEW PERSPECTIVE ON THE HEALTH OF CANADIANS* (1974).

approach assumes a constraint on both capital expenditures and operating revenues. If the corollary benefits of establishing a lid on capital expenditures and consequent health services would be to help preserve adequate funding for research and development that now face serious cutbacks as a result of the burgeoning Medicare and Medicaid programs, the present drive to establish a balanced federal budget. See, for example, the report by Sen. Edward Kennedy:

g health care costs have also hampered the ability of Federal and State govern-



teaching new health professionals and one percent for public health education), no one could calculate with any certainty how much in capital expenditures should be allowed in a specific year to reach the thirteen percent level. This would be true because of the varying and unpredictable level of operating costs that are associated with capital expenditure projects.

The arbitrariness necessarily involved in setting the level of the lid has just recently been illustrated by the federal government. In 1978 the level of the federal lid proposed was \$2.5 billion, a figure estimated as being one-half of the nation's capital expenditures for health facilities and services during the preceding year. As stated earlier, for 1979 the Carter Administration's latest proposal is for a lid of \$3 billion—an increase of nearly seventeen percent (approximately twice the rate of the Consumer Price Index during the same period). The amount of the increase has undoubtedly been prompted as much by political considerations (if \$2.5 billion failed to get congressional approval, then perhaps \$3 billion will succeed) as by any recalculation of the nation's health needs.

Officials in New York have been considering a range of approaches from using, on the low side, the average amount approved annually during the last three years under the state's CON program (estimated at \$250 million per year) to, on the high side, the annualized cost of replacing needed facilities (approximately \$400-500 million) with ten percent of the statewide cap held back by the state for discretionary purposes.<sup>147</sup>

While some experimentation on this subject may be worthwhile, implementation of such an approach should not be delayed solely because there is no unanimity among policy experts on the ideal level of an imposed lid. As in setting any budget, some arbitrariness is unavoidable. Once an initial level for the lid has been set, marginal altera-

---

ments to meet other pressing social problems. For example, between 1966 and 1978, the HEW health budget increased from \$3 to \$44.5 billion. Of this increase, \$37.3 billion has gone to pay for benefits under medicare and medicaid, with only \$4.2 billion left over for expansion of other governmental health activities beyond their 1966 level. . . .

Tragically, we are pouring so much money into hospitals right now for extra beds, for unneeded tests, for unnecessary surgery that we have not had money to spend on basic preventive health care. It is more humane, and it would be a lot less expensive, to prevent illness than to put someone into a hospital to cure them.

125 CONG. REC. S2214 (daily ed. March 7, 1979).

147. A provision to exceed the cap if the state commissioner of health finds that the lives and safety of patients would otherwise be endangered is also included in the New York plan. NEW YORK STATE BRIEFING BOOK, *supra* note 132, at 14. The New York plan identifies large multi-year projects as potential beneficiaries of the 10% discretionary fund. *Id.* at 10-11.

tions can be legislated and an indexing system could be used to peg future increases to, for example, rises in the Consumer Price Index or another appropriate index.

Less useful, but also possible, would be a flexible, non-binding guideline on capital expenditures. These guidelines might be adopted by CON programs without further legislative authorization. A self-imposed lid could serve a useful purpose as a continuing reminder to the CON reviewers that funds for health services are not unlimited and that relative need should be considered. Whether the CON reviewers would have the discipline to utilize consistently such a guideline as a decisionmaking tool, and whether providers would feel sufficiently constrained by the existence of the guideline to compete effectively against one another is difficult to predict.

While the constitutionality of CON programs has been generally upheld, a statutorily enacted cap on capital expenditures would undoubtedly be challenged and, due to the across-the-board impact on all providers, would present the courts with a more difficult question.<sup>148</sup>

---

148. The constitutionality of regulations pertaining to costs as well as quality in the private health care sector has been repeatedly upheld by state and federal courts during the past decade, most recently by the United States Supreme Court in North Carolina *ex rel. Morrow v. Califano*, 435 U.S. 962 (1978), *aff'g mem.*, 445 F. Supp. 532 (E.D.N.C. 1977). The Court affirmed without opinion a lower court decision that the certificate of need provisions of P.L. 93-641, which require that each state enact a CON law in conformity with federal requirements or suffer the loss of grant-in-aid funds for specific federal health programs, did not violate the first, fifth or ninth amendments to the United States Constitution by seeking to "convert private facilities into public facilities subject to federal regulation and 'interfer[ing] with the physician-patient relationship by rationing health resources for reasons unrelated to the promotion of high quality care.'" 445 F. Supp. 532, 533 (E.D.N.C. 1977), *aff'd mem.*, 435 U.S. 962 (1978) (emphasis added).

In its opinion, the district court, noting that there were no "real issues of contested fact" and that "the dispositive issues are legal," *id.* at 533-34, observed that if CON covered only "public construction"

the public interest in avoiding unnecessary increases in health care by reason of the addition of unneeded additional facilities could be thwarted by private construction. For this reason, every court which has considered the constitutional validity of state certificate of need laws has found . . . the inclusion of private construction within the law's coverage valid and reasonable, save in the North Carolina case [*Aston Park*] already cited.

*Id.* at 536. The court thus found it necessary to an effective CON program to cover private as well as public health facilities if the "public interest" of cost-containment was to be addressed in a meaningful way. It barely mentioned that private investment decisions in the health industry about development and expansion would be curtailed by governmental decisionmaking. Further, the court did not rely on quality of care considerations to bolster its ruling, even though quality of care has long been an area in which the state's power to regulate the private health industry has been uncontested, and it is now commonly understood that avoiding duplicative health services often will have a significant and beneficial impact on quality as well as costs. Finally, the court found that there was no basis for the claim that CON constituted an unlawful invasion of the patient-doctor relationship. *Id.* For other cases supporting the constitutionality of CON laws, see *Simon v. Cameron*, 337 F. Supp. 1380 (C.D. Cal. 1970); *Merry Heart Nursing & Convalescent*

Nonetheless, were the Congress or a state legislature to find the establishment of a lid on capital expenditures to be necessary to contain costs, and were the lid reasonable and based on factors such as those being weighed in New York, then the reasoning relied on in recent judicial decisions upholding CON programs in general should still be sufficient to uphold the validity of a properly enacted capital lid.<sup>149</sup>

---

Home v. Dougherty, 131 N.J. Super. 412, 330 A.2d 370 (1974); Attoma v. Dep't of Social Welfare, 26 App. Div. 12, 270 N.Y.S.2d 167 (1966). But see In re Certificate of Need for Aston Park Hosp., 282 N.C. 542, 193 S.E.2d 729 (1973).

149. An interesting problem might be created if Congress enacted a national lid and a state, either before the federal enactment (as perhaps in New York or Maryland) or after it (if, for example, a state legislature in a western state believed that the federal formula for allocating expenditures failed to give due regard to its projected population growth), passed a capital expenditure lid whose provisions were inconsistent with the terms of the federal act. An uncritical reading of the recent decision in *Park East Corp. v. Califano*, 435 F. Supp. 46 (S.D.N.Y. 1977), which involved a small private hospital in New York City, would suggest that, despite the traditional hegemony of the states in the area of health care regulation, federal preemption of the state lid might now result. The hospital in *Park East* challenged a delicensure action instituted against it by the state health department on the grounds that it was actually a decertification action and that the specific procedures for such actions mandated under P.L. 93-641 had not been complied with. The state licensing agency, which was also the SHPDA, asserted that not only were its actions based on relevant licensure factors—specific violations of state quality of care standards—but that even if it were seeking to decertify the hospital for cost-containment reasons this action was authorized under the state's own decertification statute. The court ruled in favor of the hospital, holding that P.L. 93-641 had preempted the state's decertification process and, for all intents and purposes, its delicensure powers as well, because their efforts had been "motivated by a desire to eliminate excess hospital beds in New York State in contravention of the Act." *Id.* at 50.

The *Park East* opinion is troubling and, I believe, wrong for several reasons. First, nowhere in the legislative history of P.L. 93-641 is there any indication that Congress intended a federal preemption of all state initiatives in the field of health planning (§ 1526 of the Act even expressly authorizes special grants for states to conduct rate review experiments). Second, any hospital under threat of closure for reasons relating to poor quality care could invoke *Park East* if it happened to be located in an area deemed to have a surplus of beds (as most areas of the country are now believed to have). It could seek injunctive relief to prevent any state delicensure action for as long as the HSA takes to render a decision on the "appropriateness" of the facility in question. This could take a minimum of several years. Thus, the state's authority to regulate hospitals and ensure their compliance with state health and hospital codes could be seriously undermined, despite language in *Park East*, *id.* at 55, specifically stating that its decision would not affect the state's "inherent police powers" to ensure quality of care in health facilities.

The present status of *Park East* is unclear. It has been widely criticized, but has not been appealed by the state. While it appears to be a poorly decided case, if it does signal a new willingness on the part of federal courts to give such overriding deference to federal enactments, then the long-time domination of the states in the field of health care that began to erode with the passage of Medicare and Medicaid may be crumbling further.

Should the *Park East* ruling prove persuasive to other federal courts, the provisions of the federal lid would, whenever the state law was inconsistent or silent, take priority. If the case is given a more narrow reading and limited to situations in which the state officials may not have had clean hands, then a different result may be reached. The states might argue that the ninth amendment grants the states sovereign authority in this area. See, e.g., the short shrift given to the ninth amendment argument 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). But see *Wing & Sifton, Constitutional Authority for Extending Federal Control Over the Delivery of Health Care*, this Symposium, at text accompanying notes 72-112.

C. *The Plan's the Thing: Relating an Applicant's Long Range Plan to Its CON Projects*

Requiring that a facility include any proposed CON project, except for emergencies, in an institutional plan operational for at least one year in advance has significant merit.<sup>150</sup> By providing notice beyond what is now offered in some states by the letter of intent,<sup>151</sup> it alerts the CON reviewers and planners to the possible need for developing or updating review criteria or plan sections related to the proposed project.

If it is a public document,<sup>152</sup> the institutional plan also alerts other providers to the facility's intentions, opening the way for negotiations among the community's providers to offer jointly the service in ques-

---

To the extent that the sanctions levied against those hospitals that violate the federal law are limited to Medicare (a totally federal program) and Medicaid (a mixed state-federal program under which the federal government assumes a majority of the program's costs), then it is likely, following the reasoning of *North Carolina ex rel. Morrow v. Califano*, that the federal law would supersede the state's. The court in *Morrow* upheld the right of the federal government to attach conditions to health grants made to the states under federal health programs. This reasoning would certainly apply to the federal Medicaid funds. As for Medicare, this program is totally under federal control—both financially and administratively—and consequently the Congress can apparently make whatever policy decisions regarding the program that it deems proper.

150. See generally Massachusetts Department of Health, Massachusetts Hospital One and Five Year Plan FY 1978-1982, Vol. I, Background and Purpose, (1977). Massachusetts requires both a one-year and a five-year plan, although only the one-year plan is binding for CON reviews. Here is a description of the two documents:

The one year plan is a formal planning document setting forth the actions which the hospital plans to take in the forthcoming fiscal year in furtherance of the five year plan being submitted at the same time. This plan shall, at a minimum, identify all projects planned for the forthcoming fiscal year which will require a determination of need; present data supporting the need for each planned project; estimate the impact of each planned project upon current utilization patterns; state the relationship of each planned project to the hospital's five year plan; report on the progress and impact to date of projects undertaken pursuant to determinations of need granted within the last five years (or earlier in the case of any projects which have not yet been completed and in operation for two years); and include the capital and operating budget for the hospital during the forthcoming fiscal year.

The five year plan shall be a formal planning document projecting the purpose and goals of the hospital for at least the next five years in light of the major health care requirements of the population within the hospital's service area. The plan shall, at a minimum, describe the hospital's planning process; give a demographic profile of the hospital's service area, and identify major health care requirements of the population; describe the physical plant and the services of the hospital with patient origin and utilization data by major services; estimate the impact of major external forces upon the hospital's services; identify alternative courses of action, with preferences or selections stated and reasons given for each; identify preferred or selected courses of action which might require a determination of need; and describe the procedure to be followed in assessing the likely impact of the preferred or selected courses of action.

*Id.* at 1. See also Medeiros, *supra* note 54.

151. Regarding the 1122 program, see 42 C.F.R. § 100.106(a)(1) (1978).

152. Under the provisions of 42 U.S.C. § 300m-1(b)(6) (1976), public access to the files of the SHPDA is guaranteed.

tion or to arrange for a trade-off of services among the facilities. This would be more likely if a capital expenditure limit were also imposed. Other facilities can also better prepare critiques of the project with sufficient advance time, or else schedule their own competing applications for the service in question and thus open up the prospects for "batching." Batching offers the possibility of comparing the relative merits of several comparable projects all seeking to address the same community need when the community's need can be adequately filled by any one of the proposed projects.<sup>153</sup> Here as elsewhere, competitive forces can supplement the effectiveness of the CON regulatory scheme.

In addition, an institutional plan is likely to improve the internal planning capabilities of health facilities—long a neglected area even though other large and complex economic organizations in the nation have bolstered their planning capabilities.<sup>154</sup> Such planning efforts should also be useful in providing administrators and trustees with increased management control over the institution's future vis-à-vis the medical staff, the sector within the hospital that is the usual initiator of CON proposals.

Once emergency situations have been exempted, a legislative requirement that projects first be cited in plans on file with the CON reviewers should easily withstand constitutional challenge.<sup>155</sup> Absent an express grant of legislative authority, rulemaking efforts on this matter may even be sustainable as consistent with the general intent of CON to ensure the reasonable development of a state's health care system. Additional legal authority for such rulemaking efforts can be found in those state CON laws containing language dealing with re-

---

153. *See, e.g.*, *National Nephrology Foundation v. Dougherty*, 138 N.J. Super. 470, 351 A.2d 392 (1976); *Saint Joseph's Hosp. v. Finley*, 153 N.J. Super. 214, 379 A.2d 467 (1977), *cert. denied*, 75 N.J. 595, 384 A.2d 825 (1978). The proposed New York regulations, § 710.11(a), Subchapter C, Chapter V, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York establish review periods for project types whereby specific projects may be considered only during a limited time in a year. For example, all hospital tertiary service projects may be heard only from January to April of each year. This constraint on scheduling obviously leads to a batching of like projects, allowing for a comparative analysis of their merits, including quality, accessibility and costs. *See also* *Bio-Medical Applications of Clearwater, Inc. v. Department of Health & Rehabilitative Services*, [1979] 3 MEDICARE & MEDICAID GUIDE (CCH) ¶ 29,559 (Fla. Dist. Ct. App. Feb. 23, 1979) (failure of CON agency to consolidate and conduct comparative hearing for two opposing bona fide, timely and mutually exclusive applications for the establishment of kidney dialysis facilities in the same area was material procedural error; case remanded).

154. *See, e.g.*, Massachusetts Department of Health, *supra* note 150, at 2.

155. *See* the discussion of *North Carolina ex rel. Morrow v. Califano*, *supra* note 149.

view criteria that reference a project's conformity with the long-range plans of health care institutions.

*D. Of Approvals—Partial and Conditional*

It is not uncommon for CON applicants to present for review multifaceted projects that may entail both new equipment and construction, include several different service areas, or contain a mix of new services and building renovation projects. Frequently, these projects may be completed in stages extending over several years. Such proposals tend to carry a high price tag, and not uncommonly, they may include some components that are meritorious and others that are of dubious value. The common response by CON reviewers to such projects is to seek to identify as early in the process as possible those components that are of questionable utility and negotiate with the applicant to have these deleted.

The capability to negotiate reductions in project scope tends to vary with the nature of the proposal, the credibility of the CON reviewers, the project's importance to the applicant, and frequently, the likely outcome if the compromise is rejected. Under the present system, it is always the applicant who has the power to determine whether to compromise or to proceed with the original proposal. When negotiations fail, in whole or in part, the CON decisionmaker must then make the difficult decision whether the good points of the proposal sufficiently outweigh the bad to warrant the recommendation or granting of an approval. Politically, as well as technically, such decisions are exceedingly difficult, for saying no requires denying a proposal with some, if not many, significant merits.

To respond to these dilemmas, the Wisconsin legislature recently passed amendments to its CON law that authorize the state CON decisionmakers to render partial approvals.<sup>156</sup> The authority to approve some aspects of a project while rejecting others provides the CON reviewers with a significant tool, albeit one that may be double-edged. On the positive side, the reviewers need not wait passively for the applicant to decide whether or not to negotiate. Furthermore, under the prevailing system, once the applicant does agree to participate in negotiations, the burden tends to shift to the reviewers to make a comparable gesture by yielding on some of its demands for the project. Under a Wisconsin-type scheme, the applicant can neither expect nor seek, ex-

---

156. WIS. STAT. ANN. § 150.06(3) (West Cum. Supp. 1978).

pressly or implicitly, any concession in the stringency of the review for agreeing to negotiate. When the reviewers are empowered, with or without the consent of the applicant, to reduce the scope of a project, no such *quid pro quo* can be expected. Should a compromise prove impossible, the CON reviewers can still approve the meritorious components of the project without rejecting the entire proposal.

On the negative side, applicants may seek to overwhelm the CON system by "trimming out the Christmas tree"—filling CON proposals with large numbers of components—some needed, some not—to force the reviewers to search for, identify and approve necessary elements while rejecting less meritorious components. A large portion of the reviewers' limited time could thus be spent in unproductive work. Also, much of the present incentive to negotiate questionable aspects of CON proposals could be dissipated if providers perceive that the negotiation requirement has been replaced by a CON decisionmaking system that provides for partial approval. This was one concern voiced by Wisconsin state officials after they were given the new authority to grant partial approvals.<sup>157</sup> At this time it is impossible to assess the full impact of the new Wisconsin law.

Conditional approvals for CON are more commonplace, although they are frequently not recognized as such. Whenever a CON proposal is approved, the decision is based on representations found in the application—for example, that  $X$  new beds will be established, that the occupancy rate will be eighty-five percent, that residents of three contiguous counties will be served, or that a CAT scanner will be installed serving an average of  $Y$  patients per day at a cost of  $Z$  dollars per scan. Such representations are an integral part of every CON application and constitute a critical part of the record relied upon by the CON decisionmaker and appellate review bodies. This is especially true when competing applications are being evaluated concurrently, when plans and standards to evaluate a new service have not been established, or whenever there is uncertainty over such issues as the projected level of utilization, the accompanying patient charges, or the geographical area to be served. In addition, frequently as an outgrowth of negotiations with the CON reviewers, the applicant typically pledges additional actions that go beyond the specific proposal undergoing review—for example, that outreach efforts into indigent neighborhoods

---

157. Telephone conversation with Mark Knight of Wisconsin Division of Health, Department of Health and Social Services, December 22, 1978.

of rural communities will be initiated, or that an underutilized service in the same institution will be scaled down or eliminated.

Such commitments and projections may be said to constitute the conditions upon which the CON has been issued. It has been generally held that the power to approve includes the power to condition that approval, and the enforceability of these conditions has been upheld as long as they are reasonably necessary to effectuate the purposes of the statute.<sup>158</sup> Problems arise in the CON system, however, because of present inadequacies in assuring compliance with provider promises. As noted earlier, post-award monitoring of CON approvals is virtually nonexistent in most states. At the present time, neither Medicare nor Medicaid collect the data to cross-check actual levels of utilization with projected levels or to compare the amount of actual billed charges with the charge estimates presented in the CON application. Private third-

---

158. The analysis of conditional CON approvals prepared by Colorado Assistant Attorney General Frederick Yu is most instructive on this point. In a Memorandum to Colorado Health Facilities Review Council (September 6, 1978), Mr. Yu, in reviewing the Colorado CON statute, which was silent on the matter of conditional approvals, found strong authority for their issuance.

Courts have held in a number of cases that the power to approve includes the power to condition that approval. In *Southern Pacific Co. v. Olympic [sic] Dredging Co.*, 260 U.S. 205, . . . , the Secretary of War had approved construction of a new railroad bridge over a navigable river. The Secretary's approval was conditioned upon the removal of the old bridge. The U.S. Supreme Court said:

That the Secretary of War was authorized to impose a condition heretofore quoted does not admit of doubt. The power to approve implies the power to disapprove, and *the power to disapprove necessarily includes the lesser power to condition an approval*. In the light of this general assumption by Congress of control over the subject and of the large powers delegated to the Secretary, the condition imposed by that officer cannot be considered otherwise than as an authoritative determination of what was reasonably necessary to be done to insure free and safe navigation so far as the obstruction in question was concerned.

(emphasis added) 260 U.S. at 208.

. . . .

It is worth noting that some courts have struck down conditions attached to varied forms of licensure. For example, in *New York University v. Temporary State Housing Rent Commission*, 304 N.Y. 126, 106 N.E.2d 44 (1952), the plaintiff University sought to evict a tenant to recover a building for use as a dormitory. The Rent Commission, as a condition to the issuance of a certificate of eviction, required the University, as the landlord, to relocate the evicted tenants. The court found that nothing in the statute or regulations authorized the Commission to impose such a condition, and that the condition was therefore unlawful. . . .

Whenever the Council wishes to impose a condition upon the issuance of a certificate, it must inquire whether the condition is "reasonably necessary to effectuate the purposes, scope, or stated terms" of the Certificate of Public Necessity Act. Where the Council finds such reasonable necessity, and does impose a condition, it would be worthwhile practice for the Council to make specific findings as to the basis for its decision to impose a condition, the reasonable necessity of the condition, and how the condition effectuates the purposes, scope or stated terms of the Act.

*Id.* at 2-3. Mr. Yu's analysis was based on the Colorado Administrative Procedure Act, which is comparable to the administrative procedure acts enacted in most other states; consequently, his analysis is applicable to many state-enacted CON programs.



party payors also do not look for these discrepancies. CON reviewers themselves do not customarily monitor projects after the award, generally having neither the inclination nor the resources.

Furthermore, once significant deviations from the original application have been found, it is not at all clear whether suitable remedies are available to CON reviewers or other parties. Absent the intentional filing of erroneous information, rescission of the CON itself would be extremely difficult, especially since CON statutes are generally silent on this point. It is also unlikely that courts would favor so drastic a penalty. Civil fines might be possible, but again specific statutory authority is lacking in virtually all CON laws. Discounting future CON proposals filed by the offending applicant might be attempted informally, but again, lacking statutory authorization, a CON agency may not be empowered to sanction providers in this manner. With change frequently outpacing the best of projections in the current health care industry, fraud or bad faith is exceedingly difficult to prove when discrepancies appear.

The best opportunity for both oversight and assuring compliance with the promises of a CON application lies with a prospective hospital budgeting system, most particularly with a state hospital ratesetting commission. Such commissions are generally bound to recognize CON projects in their hospital rate setting efforts.<sup>159</sup> In some states, however—most notably Maryland—this has resulted in an element of rivalry, if not bad feelings, between the CON and planning staff and their cost-conscious, budget-watching colleagues in the state hospital commission.<sup>160</sup> Nonetheless, through the use of this financial mechanism, a hospital could be held to comply with the specific charges, utilization figures, or purchase price proposed and approved in its CON application. The hospital commission would simply recognize only those costs that would have derived from the projections in the approved application—for example, the unapproved additional costs of a construction project would be excluded from the rate base. If actual utilization levels were lower than those projected, the higher unit costs would similarly be disallowed.<sup>161</sup> The material representations made

---

159. See, e.g., COLO. REV. STAT. § 12-43.9-106(3)(c)(IV) (1978) (forces the hospital commission to recognize for a minimum of three years the full costs of a project that has received CON approval).

160. See H. Cohen, *supra* note 97.

161. Because of the high ratio of fixed to variable costs in most areas of the health sector, not allowing a hospital to raise its per unit charges when utilization is lower than expected and when

in the final (approved) version of the CON application could be binding for a minimum period such as three years—whether the commitment was made on the initiative of the provider, elicited by the CON reviewers, or was prompted by the competitive pressures arising out of a “batched” application format.<sup>162</sup>

It may be appropriate before taking remedial action—whether through a ratesetting mechanism or through other means—to apply a screen or test to the provider who might simply have erred in completing its CON application. One criterion should be whether the erroneous information was material to the deliberations—that is, did the reviewers and other interested parties rely on it to such an extent that the project’s evaluation might have been different had the correct information been provided. To return to our earlier example, how important was it that the applicant indicated that it would be serving three counties rather than two? If, given the specific facts of the case, it is judged not significant by the CON decisionmaker, then the error could be excused. Nonetheless, there could be a cumulative effect of small mistakes that totally distorts the merit of a project or raises legitimate concerns about the competence of the party filling out the application forms. Ultimately, the integrity of a regulatory mechanism is threatened by erroneous information supplied to the decisionmaker—regardless of whether the source of the mistake was negligence or bad faith.

The other criterion that should be used is whether the inability to comply with the representations in the application resulted from circumstances clearly outside the control of the provider—if for example, a radiologist expected to join the hospital staff and run the CAT scanner was delayed at his earlier post and came to the hospital six months late, resulting in the machine being utilized for this period at a rate substantially below projections. Of course, even if the provider is

---

charges had been calculated on a higher, more optimistic utilization rate may constitute a considerable financial disincentive to the facility.

162. See, e.g., *National Nephrology Foundation v. Dougherty*, 138 N.J. Super. 470, 351 A.2d 392 (1976). In besting two other applicants, the successful applicant agreed to a condition sought by the CON decisionmaker—that it operate the renal dialysis center in “cooperation” with the local hospital, which also happened to be one of the rejected applicants. *Id.* at 475, 351 A.2d at 395.

In states where there is no prospective rate setting mechanism, other remedies will have to be examined, although none is likely to be as satisfactory as the one just described. A system of graduated civil fines is one possibility. See Butler, *Assuring the Quality of Care and Life in Nursing Homes: The Dilemma of Enforcement*, this Symposium, at text accompanying notes 209-45. Partial rescission of the CON is another.

found to be free of fault, some changes in the nature of a project may be significant enough that they should be brought back to the CON reviewing agency for further disposition.

A recent Colorado case involving a 400 bed hospital in Denver illustrates this point well.<sup>163</sup> The facility applied for and received a CON in March 1976 to obtain a CAT scanner for \$450,000. The hospital found after receiving the CON that the machine it had in mind would cost \$520,000, including installation. When the hospital sent its radiologists and neurologists to both the manufacturer's plant and a large medical center utilizing the machine, they discovered that it failed to meet specifications and would not serve the hospital's needs satisfactorily. The hospital cancelled its order and began to investigate other machines, all of which were found lacking. Finally the facility discovered a "third generation" scanner that had not even been introduced when the hospital first obtained its CON. More than a year after the CON was obtained, the hospital ordered the scanner, even though it cost \$700,000 and even though CONs in Colorado were effective for not more than twelve months.<sup>164</sup> When the Colorado CON agency learned of these activities, it sought additional clarifying information. The hospital went to court seeking injunctive relief from any proposed action by the state to block the hospital's acquisition, installation and utilization of the scanner. The state court, without ruling on the merits, found that the hospital would suffer irreparable injury—though it did not indicate how—if the hospital could not immediately use its newly delivered but still unpacked scanner. The court granted the hospital's request, and the scanner began full operations.

The major importance of the case is not whether the hospital was at fault for ordering a defective brand of CAT scanner—in the area of new medical technology, models are rapidly being superseded. Rather the issue is whether the hospital should have fully disclosed its difficulties to the CON decisionmaker and obtained its consent to exceed the approved price estimate by fifty percent and the twelve-month statutory limit for incurring a binding obligation.

---

163. *St. Joseph's Hosp. v. Colorado Dep't of Health*, No. C76578 (Denver Dist. Ct. Feb. 6, 1978).

164. *See* COLO. REV. STAT. § 25-3-509(1) (1973).

*E. One Bite at the Apple: The Relevance of the Doctrines of Res Judicata and Substantial Evidence for CON Decisionmaking*

With CON approval rates nationally in the ninety-percent range, it may seem premature to discuss reforms designed to assure that the CON system is not flooded with rehearings and extensive appeal hearings regarding projects that have been rejected after a full administrative proceeding. Nonetheless, if the stringency of the CON system does increase—as its boosters assert is not only likely but presently occurring<sup>165</sup>—then the number of projects that will be denied is likely to increase markedly. This projected increase in rejections will undoubtedly give rise not only to a surge in appeals, but also to the development of “new” projects that will be nothing more than reworked versions of an already rejected project, with only cosmetic or trivial differences. These tactics are likely to be utilized primarily by wealthier applicants for whom the cost of prosecuting a CON application is relatively insignificant, especially since the costs of preparing an application are recoverable from third-party payors, including Medicare and Medicaid.<sup>166</sup>

In the judicial system such “repeat” cases would likely be subject to the principle of *res judicata* for reasons of system efficiency and economy, certainty of outcome, and basic fairness, thus assuring that all parties—regardless of wealth—get only one day in court, that the adjudicatory system is not unduly taxed, and that the decisionmaking system is dispositive of controversies brought before it with parties barred from indulging in after-the-fact forum shopping.<sup>167</sup> In administrative adjudications, however, *res judicata* has been applied only narrowly, governed by the factual identity of the specific matter.<sup>168</sup>

The traditional policy reasons for applying *res judicata* appear relevant to CON cases. Consequently, as a general approach, subject to discretionary exemptions, *res judicata* should be applied. In CON matters the significant facts and circumstances tend to be known and to be

---

165. See, e.g., Remarks of Joseph A. Califano, *supra* note 17, at 10; American Health Planning Association report, *supra* note 37, at 3.

166. See generally 42 C.F.R. § 405.451(b)(2) (1978), which recognizes as reimbursable under Medicare those “[n]ecessary and proper costs . . . which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs which are common and accepted occurrences in the field of the provider’s activity.”

167. See F. JAMES & G. HAZARD, CIVIL PROCEDURE § 11.2 (2d ed. 1977).

168. K. DAVIS, ADMINISTRATIVE LAW OF THE SEVENTIES § 18.02 (1976).

relatively constant. Review criteria and plans are increasingly common for a growing number of services and projects and, at least for the short run, are not likely to change. Thus, barring a showing of great and unforeseen hardship, a project that has been considered and rejected by CON reviewers should be barred from resubmission for a substantial period of time, such as three years.<sup>169</sup> After that period, conditions may well have changed enough to justify a reexamination of the project if it is resubmitted.

It is more difficult to establish a definite policy for once-rejected CON projects that are resubmitted after being substantially modified or economically scaled down. A subsequent proposal may be substantially different from its predecessor even though it deals with the same general subject matter. For example, suppose that a general hospital has an underutilized wing that is licensed for use for general surgery patients. *Res judicata* should not bar the hospital from submitting a CON proposal to convert the wing from general surgery uses to general rehabilitative care even if a CON had already been denied on the basis of over-capacity in the community for an earlier CON application to convert the wing into one designated for heart catheterization and cardiac surgery. Little good to the public or the institution would be accomplished by freezing the wing's use for a period of time (perhaps as long as three years), especially since, with the exception of New York and Wisconsin where the power has never been exercised,<sup>170</sup> states at the present time are without the authority to decertify (that is, eliminate) a hospital's service. The wing would, in all likelihood, be of little value as an underutilized surgical area.

Another hypothetical, however, reveals the difficulty in devising a general rule. Let us assume a hospital is seeking a CON for two million dollars to construct a new wing to add twenty new intensive care beds. It is rejected on the grounds that less expensive alternatives were not explored. The facility then returns within six months with a project estimated to cost one million dollars that would involve converting an underutilized, already existing floor of the hospital into an intensive care service for fifteen beds. Should consideration of this second proposal be barred by *res judicata*?

---

169. *See, e.g.*, 42 C.F.R. § 100.109(c)(1)(iii) (1977) (three-year limitation in 1122 program).

170. N.Y. PUB. HEALTH LAW § 2806-a (McKinney Cum. Supp. 1978). In Wisconsin the authority to decertify is limited to six specialized services: heart catheterization or cardiac surgery, radiation therapy, hemodialysis, kidney transplantation, intensive care and high risk neonatal services, and CAT scanning. WIS. STAT. ANN. § 150.41 to .48 (West Cum. Supp. 1978).

The adverse consequences of rejecting for review a less ambitious or less expensive version of an already rejected project could be considerable. It could well discourage an applicant from pursuing a more realistic approach in the first place. The incentive to settle for less, as has been noted repeatedly in this article, is already small in the health sector, especially for larger, wealthier providers. On the positive side, erecting a bar of some kind to such modified CON projects could, for appropriate projects, aid CON decisionmakers in achieving a mutually acceptable compromise with a project's proponents. Determining when to invoke such a bar and what the nature of it should be is worth further consideration and perhaps some experimentation. Conceivably, the bar should be applied whenever a new project deals with the same subject and involves no additional services, but has a lower cost or fewer beds. Or perhaps the bar should be an absolute one remaining in effect for one year rather than three, or it should be a relative one in which, operating under a capital expenditures lid, it would carry "penalty points" of some kind that would detract from the project's priority in obtaining an allocation of the state's annual budget for new capital expenditures.

Similar considerations of economy, certainty and fairness should also apply to the scope of appellate review rendered at both the administrative and judicial levels. Consequently, CON matters that have been appealed should be subject to the substantial evidence rule, so that review is limited to whether procedural due process was accorded, whether the action taken was within the agency's authority, and whether the decision was supported by substantial evidence in the record.<sup>171</sup>

The courts appear to have been diligent in exercising the self-restraint necessary in applying the substantial evidence rule to CON cases, although in several recent instances they have found the rule's minimum requirements not to have been met and have reversed the administrative decision resulting in the issuance of a CON.<sup>172</sup> The defects in several of these cases were the same—there had been inadequate documentation in the record on why a specific standard had been

---

171. *See* Saint Joseph's Hosp. v. Finley, 153 N.J. Super. 214, 379 A.2d 467 (1978).

172. *See* North Miami Gen. Hosp. v. Office of Community Medical Facilities, 355 So. 2d 1272 (Fla. Dist. Ct. App. 1978); Northwest Hosp. v. Illinois Health Facilities Planning Bd., 59 Ill. App. 3d 221, 375 N.E.2d 1327 (1978).

adopted,<sup>173</sup> and the standard had apparently been applied inconsistently to earlier applicants who, despite having violated the standard, had nonetheless received a CON.<sup>174</sup> The record in each of these cases failed to reflect what special merits these more fortunate applicants possessed or how those earlier cases could otherwise be distinguished.<sup>175</sup>

While it is true that the substantial evidence rule has traditionally been applied to limit judicial review of final administrative action, it also has applicability for administrative appellate bodies and the reviews they conduct under current CON program requirements. After reviews at the HSA (and in some cases, the sub-HSA) level and a review and final administrative decision at the state level, there is still under federal law an additional administrative review before a disputed CON matter may be brought before the courts.<sup>176</sup> This additional step, which frequently has the potential for developing into a second full hearing,<sup>177</sup> promotes neither economy, certainty nor fairness.<sup>178</sup> Pennsylvania is presently seeking to amend its 1122 contract with HEW to limit the scope of review of this administrative appeal to bring it into accord with the judicial substantial evidence rule and, at a

173. *See* North Miami Gen. Hosp. v. Office of Community Medical Facilities, 355 So. 2d 1272 (Fla. Dist. Ct. App. 1978).

174. *See id.*; Northwest Hosp. v. Illinois Health Facilities Planning Bd., 59 Ill. App. 3d 221, 375 N.E.2d 1327 (1978).

175. These recent judicial decisions regarding CON decisionmaking corroborate what Professor K.C. Davis noted in his recent work regarding the current status of general administrative law:

"Developing the record" has become the central issue for administrative law in the 1970s. The record thus becomes the critical point for assuring general political accountability to the public and the legislature and in providing the courts with the necessary legal basis for exercising their limited review over administrative actions, including rulemaking, rate setting and adjudication.

K. DAVIS, *supra* note 168, at § 6.

176. 42 C.F.R. § 123.407(a)(9), (10) (1977) (CON requirements of P.L. 93-641); 42 C.F.R. § 106(c) (1977) (1122 requirements).

177. A hearing must be held at either the HSA or state level. 42 U.S.C. § 300n-1(b)(8) (1976).

178. *See, e.g.*, Somers & Somers, *supra* note 42:

It is not easy to find a satisfactory balance between "due process," designed to provide maximum protection to the regulated parties, and administrative efficiency. In the New Jersey situation, however, it appears that "due process" has been too closely identified with multiple layers of bureaucratic review.

. . . Equity does require that denied applicants have a right of appeal within the administrative process. But such an appeal can rightly be confined to questions of "due process" to assure that all rights under the law have been respected and proper procedures have been followed. It does not require a complete reopening of all substantive questions . . . .

*Id.* at 161. For a similar perspective from California, see S. Price, *supra* note 115, at 4: "In terms of procedure, what the state lacks by way of regulatory bodies it makes up for by over-using what it has. Everything is done twice."

minimum, to bar additional testimony at this level.<sup>179</sup> At the time of this writing, this approach has not been approved by HEW. Such limits on administrative appeals seem nonetheless advisable.

*F. Keeping Future "CATs" in the Bag: The Case for Time-Limited or Site-Limited Moratoria for New Technology*

In the aftermath of the CAT scanner phenomenon, with its explosive introduction, its short-lived generations of equipment, and the lingering questions about its efficacy,<sup>180</sup> one fact emerges clearly—with a new invention, it could all happen again. The forces that push providers toward embracing proliferating technology are, if anything, stronger than ever,<sup>181</sup> and the capability of the overseers of the health system—the third-party payors, the planners and the regulators—to respond adequately to the next technological breakthrough remains minimal. Specifically, the staff of CON agencies, HSAs and SHPDAs, such as planners, statisticians, administrators and financial analysts, lack the resources and the training to conduct studies and analyze results on the effectiveness, efficacy and safety of new medical equipment. Incentives continue to exist for hospitals to compete among themselves not on the basis of price but largely through offering status and convenience (measured in part by providing the latest in medical technology) to its medical staff.<sup>182</sup> Like other Americans, especially those with scientific training, many physicians continue to be intrigued with gadgetry and interested in labor-saving devices. Furthermore, physicians are concerned about malpractice and their potential liability if they fail to provide their patients with the latest in diagnostic and therapeutic services.

The advent of the new technology assessment capability in the Office of the Assistant Secretary of Health<sup>183</sup> and the increased activities of the Office of Technology Assessment in Congress, together with university-based research efforts into the subject, may begin to provide the basis for reviewing new technology *before* its massive introduction into the field. It has been estimated that forty percent of the increase in

---

179. See Proposed Rule § 8.14 (Scope of the fair hearing) in 8 PA. BULL. 452-53, 2305-06 (1976).

180. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 100.

181. See, e.g., authorities cited note 102 *supra*. See also H. Cohen *supra* note 97, at 7 (financial incentives to health institutions to lease new medical equipment for short periods rather than purchase it outright).

182. See Nelson & Winter, *supra* note 140.

183. Health Services Research, Health Statistics, and Health Care Technology Act of 1978, Pub. L. No. 95-623, 92 Stat. 3443 (to be codified in scattered sections of 42 U.S.C.).



hospital costs is a result of the introduction of new technology; if so, then for CON and other cost-containment mechanisms to succeed, a strategy for handling technology must be developed. This strategy must include analyzing, compiling and publishing research already performed on new technology, the funding of clinical trials and other methodologies that study the effectiveness as well as the efficiency of new equipment and procedures, and researching the technology development industry as well as the receptivity of health providers to new technology. Such research is necessary first to understand and then to influence the development, the deployment, and ultimately the use of technology in the health care sector. These issues must receive national attention. The work cannot be handled piecemeal without an overall coordinating point.

CON agencies must learn how to monitor closely the work of these national research projects and establish checks on the deployment of new technology until adequate evidence has been collected and evaluated on the usefulness of the projects. A limited moratorium may provide the best basis for evaluating some kinds of technology. By setting up one site in a state or region for public use of the new technology, the service can be made available on a limited, experimental basis while the usefulness of the technology is being fully examined. Alternately, a time-limited moratorium could be imposed, precluding any introduction of the technology into the state until evidence has been collected nationally showing it to be safe, efficient and medically cost-effective.

Precedents exist to support moratoria for planning and CON purposes;<sup>184</sup> however, several recent state court decisions suggest that it is questionable whether a moratorium could be imposed without formal rulemaking procedures.<sup>185</sup> Furthermore, to establish the prima facie reasonableness of the regulation, the agency should clearly set forth in the rulemaking hearing the purposes it hopes to serve by enacting the moratorium and the procedure to be utilized to review CON applications for the service in question.<sup>186</sup>

---

184. *See* Cooper River Convalescent Center, Inc. v. Dougherty, 133 N.J. Super. 226, 336 A.2d 35 (1975).

185. *See* North Miami Gen. Hosp., Inc. v. Office of Community Medical Facilities, 355 So. 2d 1272 (Fla. Dist. Ct. App. 1978); Cooper River Convalescent Center, Inc. v. Dougherty, 133 N.J. Super. 226, 336 A.2d 35 (1975).

186. *See* Cooper River Convalescent Center, Inc. v. Dougherty, 133 N.J. Super. 226, 336 A.2d 35 (1975).

## CONCLUSION

The solutions proposed in this article to strengthen the CON system are admittedly wide-ranging, eclectic, and in some areas, perhaps radical. The proposed remedies all tend to require greater intervention, but they are not merely premised on the assumption that all aspects of the health care industry should be brought under regulatory scrutiny and control. Several proposals were designed to bring efficiency, accountability and initiative to the CON mechanism. Others were aimed at stimulating market forces in the health care system and diffusing political opposition to sound but locally unpopular CON decisions. Some approaches sought to raise the consciousness level of parochial providers and consumers alike while protecting the right to due process of all interested parties. Finally, options were proposed to allow the system to function—or at least “muddle through”—until the quality and availability of health information, plans and criteria can be improved.

CON cannot be the panacea for the inflation that now ails the health care system. The roots of the problem are too numerous and too ingrained in our entire economy to be addressed by any single approach. CON is, at best, only a tactical device. Efforts to reform CON cannot take the place of efforts to develop a national health policy. However a national health policy is formulated—whether through the marketplace, centralized planning, or some mixture of both—it must establish priorities for the nation’s health care system. We must seek to obtain better value for our current health expenditures. CON, together with other tools, may prove useful in administering priorities, eliminating waste and redundancy, and giving us better value for our health dollar.

