Critical Experiences in Organizing and Administering a State Certification of Need Program

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ALTHOUGH RELATIVELY NEW to the health planning armamentarium, the regulation of capital expenditures through certification of need (CON) is now well established. The origins, prevalence, and coverage of such legal controls, the rationales supporting them, their strengths and shortcomings have been, and will doubtless continue to be, actively discussed (*1–10*). Analyzing the results of the first 19 months' experience with a State CON statute in Massachusetts, we commented on the formidable hinderances to assessment of CON and concluded that "as a consumer-oriented regulatory tool, it is valuable though limited, since it can only react to proposals and can neither initiate nor provide positive incentives for new programs" (*11*).

Weaknesses notwithstanding, CON marks the culmination to date of efforts to expose a hitherto private process—health care providers' long-range decision making—to public scrutiny and accountability. The 1966 comprehensive health planning legislation (Public Law 89–749) established planning by consensus, but set up no direct links to resource allocation. Section 1122 of the 1972 Social Security Amendments, limiting Federal participation in unnecessary capital expenditure, began forging the planning-resource allocation links. Public Law 93–641, the new national health planning act, apparently reinforces those links while strengthening the authority for certification of need.

Controversial, highly visible, and hence vulnerable, CON has nevertheless secured a foothold. Because the process forces all parties to alter customary practices in ways that may foreshadow the future directions of health planning, its specific details—questions of equity, procedure, and participation—have special salience. In this article we examine critical issues in organizing and administering the Massachusetts CON program, a vigorous program established by the State legislature in November 1971 in a temporary emergency law (*12*), which was later revised and enacted as a permanent statute (*13*).

Generalizing from the Massachusetts experience, we observe that the consumer's influence on final decisions may be illusory and that the provider, for all his discomfort, still holds all the trump cards.

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Background and Early Results

All health care facilities in Massachusetts must apply to the State department of public health for a certificate of need in cases of original licensure and of (*a*) a capital expenditure exceeding $100,000, (*b*) the addition of four or more beds, and (*c*) a substantial change in services (which may involve no capital cost), with the special exemption for nursing homes of a decrease in the level of care.

The statute leaves the definition of "service" and most procedural matters to administrative regulation by the department but delineates the CON program's mission: to "encourage appropriate allocation of private and public health care resources and the development of alternative or substitute methods of delivering health care services so that adequate health care will be made reasonably available to every person within the Commonwealth at the lowest reasonable aggregate cost" (*13*).

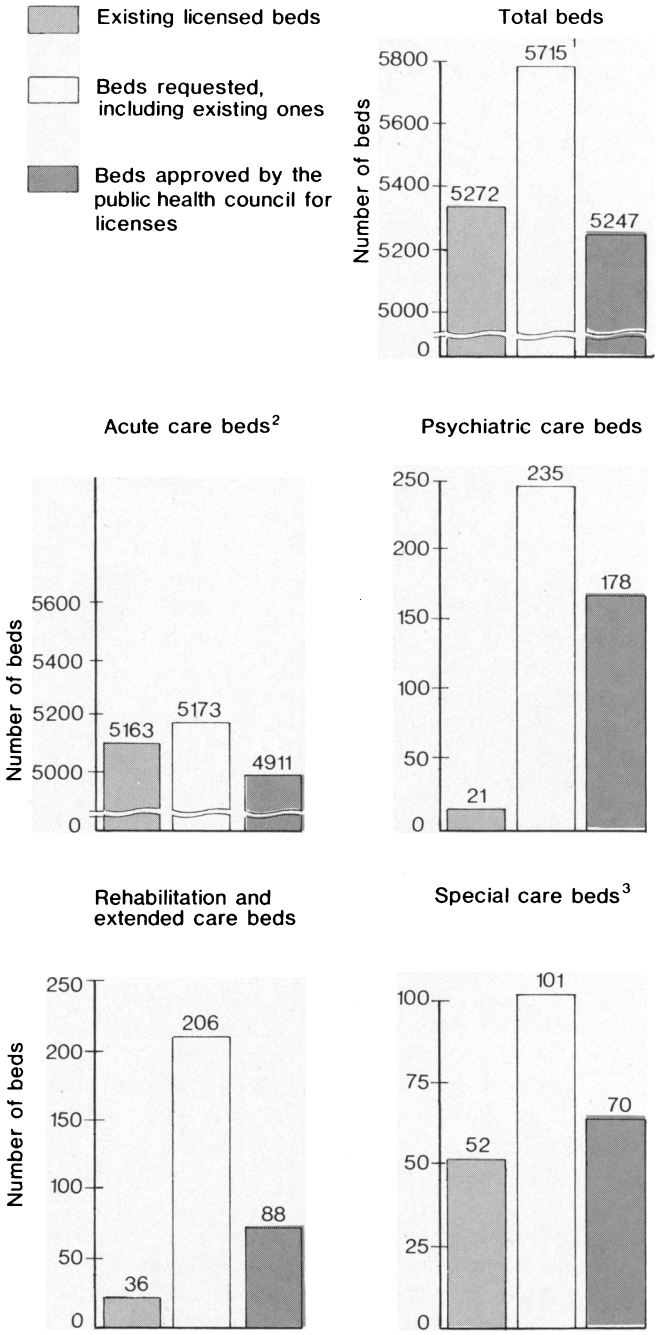
Table 1. Determinations of need for applications acted upon by the Massachusetts Public Health Council between June 1, 1972, and December 31, 1973

Projects	*Number*	*Percent of total*
Beds in general hospitals	21	10
Beds in long-term care facilities[1]	107	51
Facility improvement	40	19
Clinic	37	18
Special[2]	4	2
Total	209	100

[1] 101 nursing homes, 4 chronic disease and rehabilitation facilities, and 2 applications for change in status from nursing home to chronic disease hospital.
[2] Infirmaries, renal dialysis services.

In our quantitative analysis of the results of the first 19 months (*11*), we found that of 209 projects (table 1) acted on by the Massachusetts Public Health Council, the majority (128) involved beds, either in acute care general hospitals (21 projects), or in long-term care facilities (107 projects). In the general hospital sector (fig. 1), the council's determinations implied a potential decrease in capacity of 468 beds, accomplished by precluding the addition of 443 new beds and reducing the existing beds by 25. When we analyzed beds by clinical services (fig. 2), it appeared that the council was most rigorous as to the medical-surgical service; these applicants as a group proposed to increase their total bed complement by 23 and were, instead, required to decrease it by 172 beds. The council's long-term care determinations (fig. 3) apparently prevented the addition of 1,885 beds, although the thinking behind this outcome is less easily summarized, owing to early uncertainty about objectives and to gaps in the council's knowledge about long-term care facili-

Figure 1. Beds in 21 general hospitals seeking certificates of need in applications acted on between June 1, 1972 and December 31, 1973



[1] Of 21 applications, 10 were approved in toto, 7 in part, and 4 were denied.
[2] See figure 2 for breakdown by service of beds in acute care hospitals.
[3] Beds for treatment of diabetes and alcoholism.

Figure 2. Acute care beds in 21 general hospitals seeking certificates of need in applications acted on between June 1, 1972 and December 31, 1973, by service

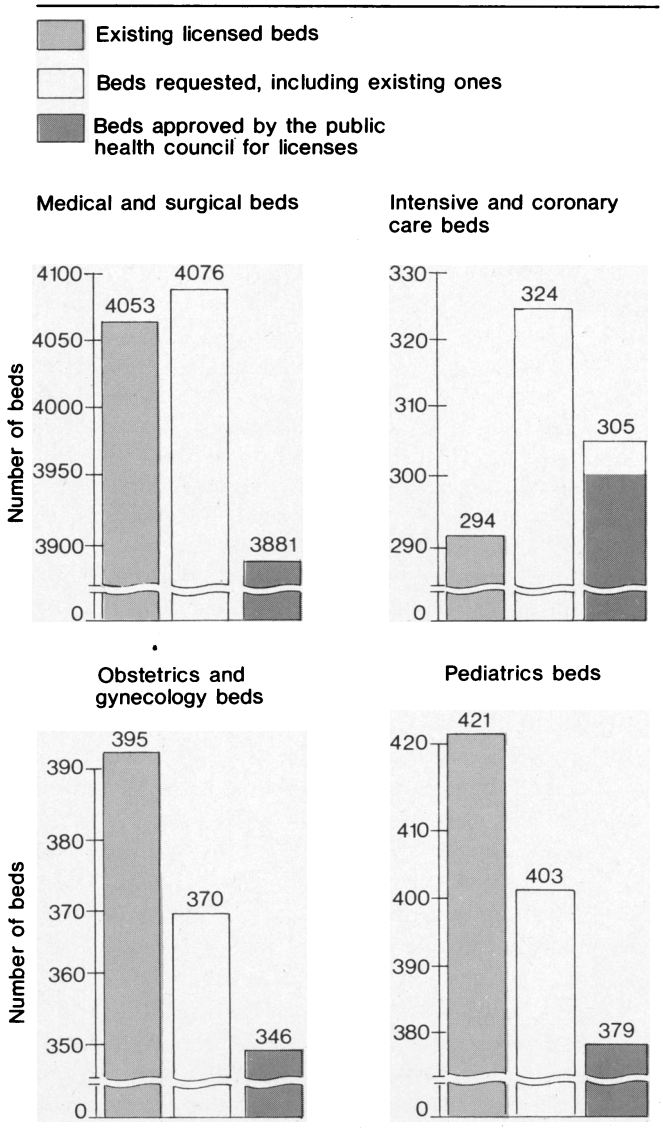
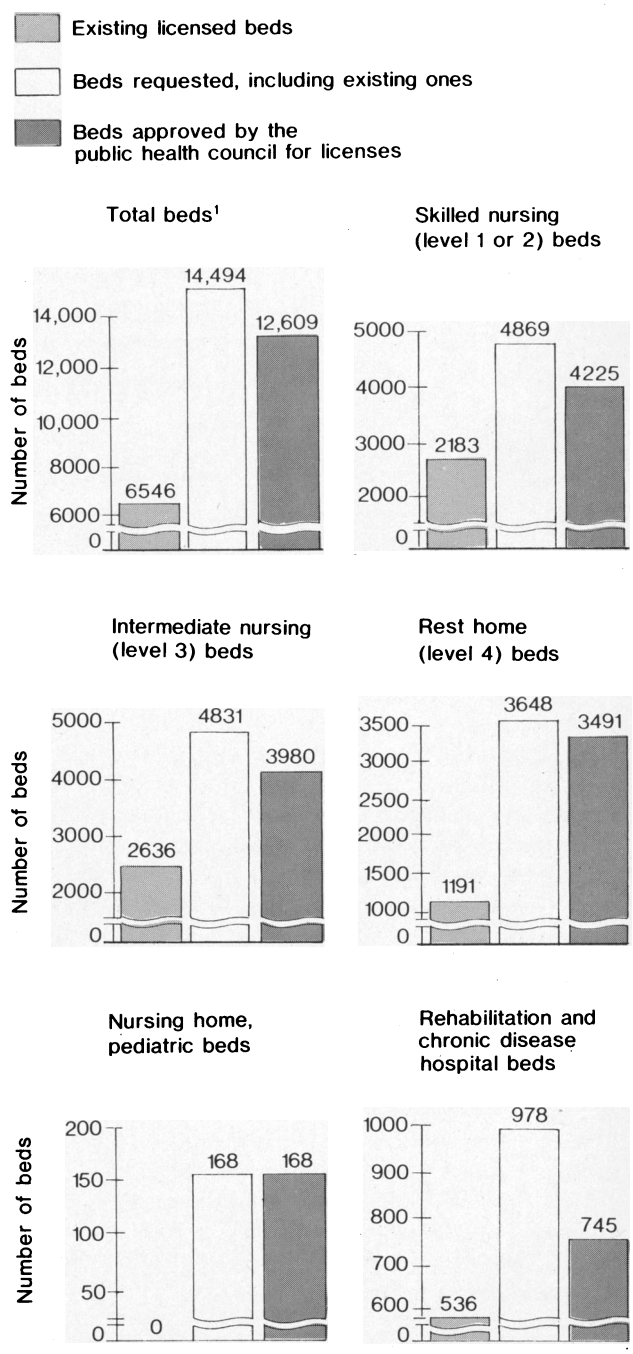


Figure 3. Beds in 105 long-term care facilities seeking certificates of need in applications acted on between June 1, 1972 and December 31, 1973



[1] Of 101 applications from nursing homes, 65 were approved in toto, 15 in part, and 21 were denied. Of 4 applications from rehabilitation and chronic disease hospitals, 3 were approved and 1 denied.

Table 2. Procedures and roles of the participants in the Massachusetts certification of need process

Procedure	Applicant	Department of public health staff	CHP "a" and "b" agencies, 10-taxpayer groups, and elder affairs [1]	Public health council	Health facilities appeals board	Courts
Application	Initiates	Receives	Receive copies			
Review process		Prepares report summarizing all pertinent commentary.	May comment			
Public hearing	May request	Commissioner can call. Staff prepares summary.	May request			
Action within 120 days.		Based on staff summary and recommendations.	May recommend: public health council must consider such recomendations.	Makes determination. Final action—preliminary, dismiss, deny, or award (all or in part).		
Appeal (of award or denial).	May initiate		May initiate		Examines whether public health council abused discretion, violated statutes or regulations.	Judicial review (any health facilities appeals board ruling may be appealed.

[1] Elder affairs department participation limited to long-term care applications.

ties. The department has been working to close some of those gaps.

Having undergone three major revisions, the current regulations (summarized in table 2) delineate roles for the applicant, the State and areawide comprehensive health planning (CHP) agencies, the State department of elder affairs (in long-term care determinations), and any group of 10 or more taxpayers. The 10-taxpayer group can be an established organization or an ad hoc association of any 10 people who register with the department to participate in a given determination. Consumer groups, as well as competing providers represented by 10 persons, can and do file as 10-taxpayer groups. They thus attain equal standing with the applicant and the CHP agencies, including opportunities for review and comment, presentation at hearings, and appeal of decisions.

Final decision-making authority rests with the State's public health council, a quasi-independent body in the executive branch of State government. Chaired by the commissioner of public health, the nine-member council is by law the department, and as such sets overall policy through the promulgation of regulations and can decide how actively it will participate in particular decisions. The council chooses to rule on every CON application, usually on the basis of a detailed staff summary which is prepared by the program analysts of the department.

The Agency as Tightrope Walker

The emergency legislation enacted in Massachusetts in 1971 emanated from a perception that hospital bed capacity in the State was seriously overdeveloped (*14*) in comparison to that of most other States and other regions of the United States (*11*). An overabundance of hospital beds complicates the administrative task of introducing a new CON program. That task is least onerous when additional beds are needed and the program must encourage thoughtful and foresighted decisions on where and how to develop new capacity; more onerous when capacity is about right so that a steady state needs to be maintained, imbalances in the delivery system remedied, and cost consciousness fostered early in the planning process; and most difficult when overcapacity is a problem in the acute care sector, when numbers of beds have to be reduced, and providers encouraged to start new programs (for example, in ambulatory and long-term care), to operate their established programs differently and more efficiently, and to deemphasize the services traditionally offering the greatest rewards (medicine-surgery, maternity, and pediatrics services in acute-care general hospitals).

In the third situation, overcapacity, CON can be implemented gradually, taking care to avoid antagonizing providers, or suddenly, with little regard for the consequences. Massachusetts took the second route.

Lacking a grandfather clause, the temporary legislation literally stopped bulldozers in their tracks and afforded providers no time to adjust to the radical concept that their freedom to make private capital investment decisions had been supplanted by complex requirements for public accountability. Predictably, the provider community was resentful.

A rigorous and consumer-oriented CON program in a jurisdiction with excess beds will arouse antagonism. How much pain can be avoided without compromising the integrity of the program? On reflection, the Massachusetts experience suggests that at least some consumer-provider polarization is probably valuable and certainly unavoidable. CON is only one of many arenas in which providers are being held to increasingly exacting regulatory requirements, but it is an early and individual hurdle, with an identifiable public process, and inevitably it acts as a lightning rod for the providers' general antipathy to regulatory intervention in the health care sector.

This reaction was most pronounced in the early months of the program, when applicants commonly viewed the State as a monolith and complained that it not only threatened to prevent badly needed renovations, but also was either delinquent on payments for publicly supported patients or making payments at inappropriate rates. The reimbursement issues implied in the latter two complaints lie outside of the department's jurisdiction, in the purview of the department of public welfare and the rate setting commission, respectively. Confusion over regulatory roles and authorities, combined with the visibility of CON, was manifest also in applications from providers seeking change in licensure status (for example, from nursing home to chronic disease hospital) to improve their reimbursement rates. The council came to recognize inappropriate applications and directed the applicants in such cases to seek redress elsewhere (for example, from the State's rate setting commission).

The importance of the confrontational approach to determining need is suggested by table 3, which lists the financial resources available to the various CON participants. To the extent that polarization can protect consumer interests in the face of this monopoly, the confrontation can serve a useful function. The consensual model, embodied in the term "partnership for health" applied to Public Law 90–174 and in the town meeting qualities of Public Law 93–641, has prevailed over Office of Economic Opportunity-style funding of conflict. Instead of supporting consumer groups as a means of countervailing provider influence, the Federal health strategy now aims at consensus by mixing provider and consumer representation on the boards of planning agencies, often giving consumers the nominal majority. But, even when outnumbered, provider representatives wield the greater influence. The interest of providers is a full-time, professional interest; their institutions stand behind them, providing

Table 3. Financial resources of participants in the certification of need process in Massachusetts

Participant	Resources (millions of dollars)
Providers	[1] 957.2
Blue Cross	364.9
Medicare (inpatient, extended care and home care)	312.9
Medicaid (hospitals, nursing homes)	279.4
Reviewers	2.73
Department of public health for CON (1973–74 budget)	.463
Comprehensive health planning "a" agency (total budget FY 1975)	.245
6 comprehensive health planning "b" agencies (total budgets FY 1975)	2.02
Consumers	0

[1] For 1973, exclusive of private insurance and direct patient payments.

easy access to technical expertise, information, and data, as well as secretarial and clerical backup, and lending them the prestige of the institution in the community and the power of the institution in employment and economic influence. As a result, ostensibly consumer-dominated health planning bodies tend to be controlled by providers.

CON, then, does not rob providers of ultimate control but it does represent a new and alien way of doing business, characterized by openness and often by confrontation. No longer can accord be reached in leisurely, often private, discussions culminating in gentlemen's agreements. Instead, plans are unveiled in well-advertised open hearings and public meetings, attended by consumers and professional health planners and with outcomes which are theoretically unpredictable. The provider senses a loss of traditional controls and of assurances that everything will eventually be worked out to his satisfaction. Realistically, however, the imbalance of resources protects the provider who has lost little but the sensation of control; most decisions go his way and, even when defeated by the CON program, he has jeopardized only his plans for the future.

This provider-protection dynamic places a special burden on State agencies administering health regulations and responsible for representing the public interest with regard to health and health care. Defining the public interest involves weighing competing claims, claims which can be aligned for the sake of discussion on a continuum with providers to the right and consumers to the left. In any confrontation, political pressures and the responsibility to represent all the people militate against the adoption of a polar position by public agencies with decision-making authority. Instead, the agencies' decisions usually fall somewhere

between the two poles staked out by special interest groups. When consumer groups are disorganized and, as table 3 suggests, inadequately (if at all) funded, the left pole remains vacant, leaving to the State agency the dilemma of whether to try to involve consumers in the discussions, for example, by taking extra pains to arrange a lively and informative public hearing. In doing so, the State subjects itself to charges of partisanship, but by failing to do so, it allows circumstances to force it to stake its middle ground well to the right of center. The conceptual framework for the decision is then narrowed, favoring the status quo and leaving little or no room for discussion of radical alternatives or real innovations. The State's inevitably middle position becomes the left pole; the final decision, in all likelihood, is well to the right of center and not in the broad public interest. Following this scenario, change comes slowly if at all and the process, by default, again falls captive to the provider.

Steering clear of provider capture, however, is a means to an end (decision making in the broad public interest), not necessarily an end in itself. CON serves at least the dual objectives of seeking first to dampen rising health care costs by holding supplies in line with need (that is, curtailing providers' unwarranted expansion plans) and second to encourage providers to plan effectively with an eye to efficient and equitable decisions about resource allocation. To improve health planning, CON program staff have some responsibility to see themselves in a technical assistance rather than a purely adversary relationship with providers. But the applicants can hire all the expertise they need—planning, legal, financial, and public relations—and recapture the costs through the existing rate structures. CON staff time spent with applicants implies costs to consumer interests, either directly intruding on the time available for technical assistance to consumers or indirectly predisposing staff sympathies toward the applicant's proposal. (Having worked closely with an applicant on a proposal, the staff will naturally incline toward recommending approval when it finally comes through the formal review process.) Strong areawide planning agencies can make the difference if they provide the applicant with the needed technical assistance and thus leave to the State level decision-making agency the more distant and potentially more objective final review and decision.

Provider antipathy to CON in Massachusetts has quieted over time. Figure 4 shows that the number of appeals from council decisions has fallen dramatically since the crescendo of indignation symbolized by the 11 cases filed in 1973. With the promulgation of permanent regulations and their refinement, and as the council has accrued a record of rigor with regard to the need for more beds, the providers have developed an anticipatory reaction. It is manifest in a self-selection process on two levels—first, discouraging application generally (because providers who cannot demonstrate need simply do not apply) and second, shifting the emphasis in proposals to facility improvement rather than beds.

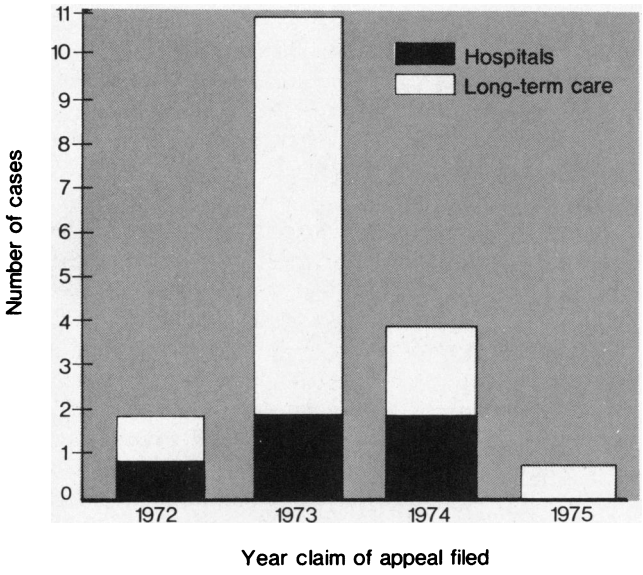
Deprived of the automatic right to build ever bigger monuments, providers look elsewhere for their status symbols—particularly to sophisticated technological gadgetry. Acquisition of complex technology may be replacing the bed as the hospital's emblem of growth and success. Subtly, the CON program's center of attention is shifting from macro to micro issues. For example, in developing criteria for computerized axial tomography (CAT) and radiotherapy, the department reasserts its position on the relationship between the capital and operating costs: that is, that the financial onus of overexpansion, whether in beds or other capital investments, falls not on the institutions deciding to build but on the public, directly through patient payments and insurance premiums for hospitalization and indirectly through tax-supported Federal and State reimbursement. First, per diem bed rates are increased to recapture construction and financing expenses and second, the design of a facility or the purchase of a complex piece of equipment largely dictates the facility's programs and, derivatively, its staffing patterns and most operating costs for the effective life of the building or the piece of equipment—function follows form instead of the reverse. A third, perhaps more subtle, economic implication is the opportunity cost associated with an investment in hospital bed capacity—diverting limited resources from the development of needed alternatives to inpatient hospitals, such as primary care and community home-care programs (*11*). The first effect is well understood. The second and third are neither understood nor fully accepted by providers and planners, but these effects are important cornerstones to the conceptual foundation of the CON approach.

The Statewide CHP Agency

The role of the State "a" agency in the Massachusetts CON program has been marked by ambiguity and confusion. Some light is shed on the "a" agency's role vis a vis other involved State agencies by the observation that the "a" agency's participation in CON is its only mention in Massachusetts State statute. The department of public health, the department of public welfare, the rate setting commission, and the insurance commission have extensive statutory authority as well as traditionally accepted roles, but the "a" agency has no explicit statutory authority within the State. Since the potential strength of CON derives from its enforcement links with licensure and rate setting authorities, the "a" agency is several steps removed from the program's source of power.

At the outset, the "a" agency formed a CON subcommittee which, from time to time, sought unsuccessfully to exercise considerable influence, without commensurate responsibility. The "a" agency's review is

Figure 4. Appeals from Massachusetts Public Health Council's determinations of need filed with the health facilities appeals board, July 1972–March 1975



separate from and parallel to that of the relevant areawide "b" agency, which sends its recommendations directly to the department, with a copy to the "a" agency. Initially, the "a" agency's analysis overlapped and duplicated those of the involved "b" agency and the department, wasting time and resources. As a result, the "a" agency moved first to a selective review of major applications and then to its current position of opting out of its review and comment role for all practical purposes.

The department has attempted to persuade the "a" agency to assume a technical assistance posture toward the State's six "b" agencies, specializing in providing the technical expertise (legal, financial, economic, and statistical) that the area agencies need but cannot afford. Instead, the "a" agency has taken on projects in a vacuum, consistently failing to perceive the futility of efforts which are not developed to be specifically relevant to decisions of resource allocation. The unfortunate result has been wasted investment with end products, such as draft CON standards and criteria, which are simply not applicable to the types of projects and issues confronting the CON program.

Situated within the executive office of human services, the "a" agency in Massachusetts has been entirely independent of the department of public health. During the first 3 years of CON, several attempts to move it into the department met with insurmountable political obstacles. With impetus from Public Law 93–641, those negotiations have been reopened. The overhead cost of unsuccessful attempts at interagency cooperation has been needless, and the opportunity cost of failures at cooperation considerable.

The Areawide Health Planning Agencies

Hampered by the same formal powerlessness that undermines the "a" agency's efforts, the "b" agencies, unlike their State-level counterpart, have found a needed and unfilled role: a vital planning function on the sub-State level. Participation in the CON process has stimulated the planning and review activities of the State's six "b" agencies and has offered them greater power to influence change than they previously possessed. The statute requires only that the department consider the comments and recommendations of local groups, but the regulations and application forms emphasize cooperative planning among providers, community groups, and CHP agencies. When a determination contradicts the recommendations of a "b" agency, the department is required to give its reasons in writing.

Seldom have the State's "b" agencies excelled in quantitative analysis; most have small staffs of generalists untrained in technical aspects of health care resource allocation. Discomfort with the quantitative side of decisions feeds a general disinclination among consumers to apply the global concept of excess capacity, with its financial and program consequences, to the particular local case. Most consumers want more (often categorical) services, not fewer; more influence on the decisions of health care providers; and better representation. The issue of a few beds, more or less, loses salience at the level of the individual project; consumers are likely to support the provider's request for additional beds if they like the total package in which it is wrapped. Providers, for their part, capitalize on this tendency by encasing their expansion plans in a total package designed to appeal to consumers. Predictably, the results sometimes undermine the object of a rationalized macro system. For example, both the 10-taxpayer group and the "b" agency subcommittee supported one applicant, a large Boston church-affiliated hospital in its request for additional unneeded beds, the department later learned, in a quid pro quo for the hospital's guarantees regarding future community services and community employment.

Ideally, "b" agencies should offer the principal vehicle for organized consumer participation in the process, and they should be able to argue with cogency and sophistication a subtle side of resource allocation arguments (for example, recommending denial of an application on grounds that there are better ways, not proposed or understood by the applicant or perhaps not within his capabilities, of meeting the need which has been demonstrated to exist). In addition, areawide review should be the pressure point at which CON can force rationalization of health planning; the State-level review is too remote and too late to shoulder this responsibility alone.

To perform these functions well, the "b" agencies—or their successors, the health systems agencies (HSAs)—need technically trained staff and technical assistance, and they must studiously avoid the temptation

of expending excessive time and resources to collect and disseminate denominator data on their region's delivery system. The umbrella responsibility for data collection must lie in a State-level agency to insure consistency, uniformity of definitions (nationally and within the State), comprehensiveness, and reliability.

At the time the CON program was implemented, the "b" agencies were required by law to generate local matching funds to supplement their Federal grants. Most were heavily dependent on hospital and other provider interests in the community for these funds. Public Law 93–641 removes the "b" agencies from the fiscal pockets of providers, a necessary refinement, but probably not a sufficient one.

The "b" agencies or HSAs could be strengthened further by amending the statute to introduce a two-step review process, on the Arizona and Kentucky models (2), in which the local determination is binding (unless appealed) if the application is denied, and tentative, pending State-level review, if it is approved. This modification seems a reasonable next step for Massachusetts. The further step of vesting the entire decision-making authority in the areawide planning bodies, however, is not yet appropriate: their purview is necessarily parochial, their technical expertise limited, and they lack the necessary enforcement links to licensure and reimbursement authorities. Conceivably, these impediments could be removed if each area's total purse of health care reimbursement funds could be centralized in the areawide agencies which would then be entrusted with overall responsibility for resource allocation, backed up by the State's technical assistance, data collection, and appeals functions. Although such a scheme is theoretical and lies in the far distant future, consolidation and unification of budget and program considerations would set in bold relief the financial trade-offs implied by a particular decision on resource allocation.

The near future for health planning is still evolving. Public Law 93–641 may resolve the conflicts between the department and the "a" agency and may strengthen the areawide review. But blurring of roles, especially on the State level, could continue if roles and functions are not worked out clearly early in the implementation of the new health planning legislation. Chaos in a program such as CON, which requires some technical expertise, will force reliance on the provider's information and judgment. Entropy will favor the large provider with resources at his command. The losers will be the smaller providers and the innovators and, in the long run, the public.

Ten-Taxpayer Groups

The 10-taxpayer group provision appears, prima facie, to complement the "b" agency vehicle for organized consumer participation. In practice, however, true consumer involvement through the 10-taxpayer mechanism has been negligible; with few exceptions, the vast majority of 10-taxpayer groups have been crypt providers. The exceptions, however, have demonstrat the value of true consumer input when the 10-taxpay group mechanism functions well. Active participati of groups truly representing a nonprovider point view has, on occasion, substantially altered the fin outcome of a determination. By taking a forceful stan to the left of the department, these groups have pe mitted the council to move its middle position co siderably to the left of its likely position had the on strong voice been the hospital's, standing to the rig of the council.

Ten-taxpayer groups, whether bona fide consum groups or not, have been relatively inactive in th appeals process. Despite clear provisions for initiati of appeals by parties other than applicants and fo challenge of approvals as well as denials, only 2 o 18 appeals filed, as of March 1975, were initiated b 10-taxpayer groups and none by CHP agencies. N approval has yet been appealed. This record suggest that consumer representation, even when numericall significant, will be inconsequential without the financia backing to underwrite the technical analysis and lega representation requisite to survival in a regulator framework—of necessity complex, highly technical and bureaucratic.

The Public Health Council

A strong decision-making body is indispensible in deter mining need. Having said that the interests of th consumer are best served by an open process or a con flict model, one must concede the limitations on th ability or willingness of a State agency to stimulat conflict. State agencies have sensitive political antennae; often their professional staffs are industry trained o industry bound, or both. There is a Catch-22 factor: the technical expertise is concentrated largely in th health care industry and CON needs the industry's skills, background, and understanding to function efficiently, but it cannot afford excessive sympathy. A decision-making body with substantial consumer representation can override the expressions of inappropriate sympathy with the industry by seeking to tone decisions to reflect broad consumer interest. However, a staff can, in fact, control both the overall process and many specific determinations by controlling the information it gives to the council or board making the decision.

By nature and composition, the council is designed to protect consumer interests by keeping decision making accessible and aboveboard. The eight members of the council, other than the commissioner, are volunteers who each receive token compensation of $600 a year plus expenses for a considerable commitment of time and energy. They attend 2 meetings a month, each lasting an average of 6 hours and each requiring another 2 to 4 hours of preparation. All nine members are gubernatorial appointees; by law, three must be

oviders of health services (two physicians), the other e nonproviders, in addition to the commissioner.

An important correlative of the council's sensitivity the consumer's point of view has been its support efforts by the more sophisticated "b" agencies to ce health care providers to coordinate and consoli- te. Again, for the CON program to function optimally, participants have to perform appropriately and cefully. Under the best of circumstances, a "b" ncy with an effective board backed by a strong staff n work in a partnership with the State to help and, necessary force, providers to make better long-range cisions than they might otherwise have made.

The public health council has played an active, ntral, and positive part in the Massachusetts CON ogram, both by directing the staff in the development fair regulations and procedures and by its rulings individual applications. Even cases which have been instakingly examined before coming to the council equently take on new dimensions in the crucible of blic discussion. On numerous occasions, the council's view has uncovered substantive issues which had caped notice at each previous level of analysis and s materially affected the outcome.

ON Support Staff—Roles and Responsibilities

ppropriations for hiring specfiic CON staff were ught by the department and denied by the legislature 1972 and 1973. A portion of the department's quest for staff was approved in July 1974 and became ailable several months later. The program continues draw heavily on positions and personnel borrowed m other departmental activities. Implementation of tification of need would have been impossible with- t Federal (314d) funds to bridge the gap between ctment of the law and allocation of operating funds. nancing remains grossly inadequate. The annual ry of the department's highest paid CON position ranged from $16,000 to $25,000, depending on aries of the State civil service, inadequate to com- with comparable hospital industry salaries. The erally low staff salaries characteristic of State em- yment, compounded by the underfunding of CON, e necessitated drawing the staff from enthusiastic ng people looking for frontline experience. Staff gram analysts frequently receive enticing job offers n applicants who, in negotiating the process, have n impressed by the capabilities of the analyst. The s of rapid turnover (five directors in 3 years) in ontinuity and repeated training of new staff may counterbalanced by a tendency for the turnover lf, by keeping the staff fresh and committed, to e as a partial safeguard against provider capture the program.

Additional staff are needed to maintain sound baseline urce data as well as to provide expertise in regu- ry law and economic analysis. From the outset, the department had the potential data collection capabilities and the requisite resource data, but it needed to improve its organizational structure and its definitions and data formats. One improvement is a Health Data Annual, published for the first time in 1974.

The collection of data to monitor the CON program has been especially difficult. The press of daily activities tends to take precedence over longer range priorities, causing them to be postponed repeatedly and to become increasingly complex. A seriously overburdened staff has difficulty taking the long view and interrupting urgent projects to record information for posterity. They feel, justifiably, that there can be no posterity if daily demands are not met. However, this view of recordkeeping obscures the importance of comprehensive data as the basis for a continuing assessment of the program, tracking trends and changes which are not obvious from a day-to-day perspective. For instance, quarterly reports of quantitative results of determinations could provide an extremely useful frame of reference for the council's subsequent decision making.

Substantial legal expertise is essential to forging links between planning and regulation. A regulatory agency derives its authority from the law. Talented lawyers with understanding of health care delivery issues are needed to translate and implement that legal authority by establishing equitable administrative practices and by integrating separate and fragmented statutes. The intellectual challenge implied, and the fact that the department's legal salaries are reasonably competitive, have made it easier to develop this capability. With the equivalent of 10 full-time lawyers, the department now has the largest legal staff, outside of the attorney general's office, of any Massachusetts State agency.

The department's attorneys have worked closely with the CON program staff to develop procedures designed to anticipate problems and obviate the need for appeals to the extent that this is possible. In refining the regulations, great care has been taken to protect each participant's right to a measured and controlled but guaranteed opportunity to speak. The department's legal staff issues advisory opinions on request, specifying the department's procedural response to a given proposal. These opinions are a formal mechanism for the department to go on record with its interpretation of a complex technical or legal issue. There have been more than 20 official advisory opinions and a great many more informal ones. The department and applicants have found this practice useful.

The attorney's importance in the CON process can hardly be overestimated. Relatively independent of the industry both for technical information and for professional mobility, and trained to understand issues of representation, advocacy, and power, the lawyers supporting the CON program staff can stand as the guardians of consumer interests. It may be an extra

challenge to create a process which, in fact as well as on paper, gives consumers more than theoretical access, and they may have to extend themselves a little to give every opportunity to the consumer, but carefully selected attorneys are uniquely suited to the task.

The department still has a distance to travel in developing capability for economic analysis. Ideally, a CON program should look at costs and all their components, regardless of sources of reimbursement. A State agency must overcome the propensity to consider a project only in terms of direct costs to the State. Operating costs which will be reimbursed by Medicare merit the same scrutiny as those involving Medicaid. The total financial picture ought to be analyzed as a cohesive unit—despite a State agency's limited capability to perform so complex an analysis.

An important distinction separates financial feasibility analysis, which ought to be within the grasp of a State agency, from economic analysis, which generally is not. Analysis of financial feasibility—whether and how the applicant will find financing—is technical and complex, but straightforward. In its early determinations, the department lacked the sophistication to make this analysis, but it has now developed at least the rudimentary methods. Economic analysis, on the other hand—the macro-questions of the implications of regulatory decisions for the performance characteristics of the delivery system—is conceptually difficult. The implications of operating costs have always been of concern to the council, but the department's ability to forecast accurately long-range effects on costs and programs of alternative program and reimbursement packages has lagged behind the council's interest. It would be useful for the department to possess the analytic capability to cost out alternative organizational and programatic approaches to meeting a need for services determined to exist, particularly in the long-term care sector, where providers are not spontaneously developing and proposing the badly needed alternatives to the traditional multilevel nursing home. However, a methodology for costing out alternatives has yet to be developed even for the general hospital sector where the technical sophistication being brought to bear on problems is greatest.

Establishing Fair and Timely Procedures

Massachusetts' Administrative Procedures Act enunciates a basic framework for promulgating regulations. An administrative agency drafts proposed regulations and presents the draft at public hearings. Public comments are incorporated in a redraft which may then go back to public hearing or be adopted formally, for the department, by the public health council. After adoption the regulations have the effect of law. If taken seriously, the process is lengthy and laborious, extending over a minimum of 6 months.

In practice, once again, special measures are required to prevent excessive provider influence. As a conscious strategy to stimulate participation in the promulgati of regulations, the department occasionally adopts extreme position in its proposed regulations, then tal pains to call the proposal to widespread attenti particularly the attention of those who are most lik to object to it. The threat of repugnant regulati motivates involved parties and special-interest grou to formulate and articulate thoughtful comments opposition to the proposals.

With the procedure poorly understood, howev the publishing of draft regulations can arouse pan embroiling the administrative agency in controver Instead of allowing this to happen, the departme can head off conflicts by achieving an informal co sensus on the draft regulations before making the public in preparation for open hearings. However, doing so, the department would cheat the consum who has neither the time nor the expertise to partic pate fully in slow negotiations over complex regulation and would allow the parties who negotiated privately avoid taking a public stance which subjects them open scrutiny and critique.

A delicate balance must be maintained by the Sta agency engaged in preparing regulations. It mu solicit sufficient technical consultation prior to publi hearings to insure the accuracy of the facts unde pinning the draft regulations, but it must also sto short of drifting into negotiation and partial or implici commitment to privately negotiated solutions. As on means of circumventing the danger of negotiation, th department has formal mechanisms for dealing wit commentary presented in public hearings. Summarie of the hearings, prepared for the council by the staff highlight all the issues raised and positions taken. Th council requires the staff explicitly to acknowledg and respond to every point made.

Standards and Criteria

In developing administrative regulations, the greate challenge is balancing the importance to applicants o fair and timely procedures against the interests of th public. Conditions imposed on certificates of nec raised problems (and hackles) in CON's early months issues related to the time-frame for decision making revocations, and cost overruns have surfaced periodi cally. But undoubtedly the thorniest problem to con found the development of CON regulations in Massa chusetts has been the question of standards and criteria

The department has been under intense pressur to formulate quantitative decision-making criteria a rapidly as possible, but the staff has wanted to resis the danger of misplaced or artificial precision befor the dimensions of the issues are throughly understood With or without full understanding, however, deter mining need is inescapably quantitative: whether o not quantitative standards are applied explicitly, th final decision—the bottom line—on every determina tion either directly states or ultimately implies a quan

Criteria for Determining Need

1975 Massachusetts Certificate of Need Regulations

"In taking final action . . . the Department shall consider such of the following factors as it deems relevant to making an appropriate determination of need on a particular application. A finding adverse to the applicant regarding any of these factors shall be sufficient to constitute grounds for denial of an application for determination of need.

(1) Whether the applicant's planning process has been thorough as evidenced by: (a) its documented consideration of transfer agreements, referral mechanisms and alternatives to the proposed projects (including expanding hours of utilization of its present service); (b) its investigation of utilization of existing resources in the area and documentation of projected demand for proposed services; and (c) its willingness to involve the appropriate regional c.h.p. agency, concerned local groups and other proximate health care facilities in its planning process.

(2) Whether the project, when completed, will comply with all relevant state and federal standards for approval, licensure or certification.

(3) Whether the existing health care services in the applicable service area are adequately providing the service contemplated by the proposed project so that favorable action on the application would result in a needless duplication of services.

(4) Whether, after using reasonable tools for projecting need including, where relevant, occupancy rates and average lengths of stay, there is need for the project applied for.

(5) Whether the applicant, after having been given [specified] procedural safeguards . . . has failed to demonstrate to the satisfaction of the Department that it is suitable and responsible to establish or maintain a health care facility or that the project upon completion is likely to meet the licensure requirements of the Department.

(6) Whether the applicant has demonstrated . . . that, in executing the project, all feasible measures shall be taken to avoid or minimize damage to the environment.

(7) Whether the applicant has considered alternative methods of construction design, operating systems and staffing patterns, as well as alternative sources of debt financing, so that the approach chosen is consistent with the Department's objectives in making determinations of need.

(8) Whether the estimated range of capital expenditure and anticipated operating costs for the proposed project are reasonable both in terms of their likely effect on the facility's per diem rate and in terms of their comparison with costs for similar projects.

(9) Whether . . . the applicant demonstrates that the project is financially feasible, and, if relevant, that the applicant has the capability to complete the proposed project and to operate the facility when completed.

(10) Whether approval of the project is necessary in order to satisfy special geographic factors, to meet acute seasonal variations in population, to meet the needs of a special mix of patients, or to encourage the development of innovative approaches to the delivery of health care services."

Proposed in draft 1975 regulations (October 22, 1974)

"In determining the need for construction of, replacement of, additions of or changes of services of beds in a hospital, the Department shall ascertain for each service the number of beds the facility requires in order to service its projected service population for 1985. In making its determination, the Department shall consider, on a service by service basis, the number of days of service per individual in the projected service population as well as occupancy rates and average lengths of stay."

Proposed in introduction to 1973 regulations

"1. A statewide *acute bed utilization rate* of 1.0 patient days per person per year by 1978 and .8 patient days per person per year by 1985. Individual projects would be evaluated in light of their contribution to the achievement of these overall goals for the health system within the Commonwealth. These figures may require adjustments for age, sex, and income, and would relate to a population projection derived from the 1970 decennial census.

2. In addition, acute general hospitals would be expected to operate at an *overall occupancy rate* of 90% and long-term care facilities at an overall rate of 95%."

titative result (for example, a certain number of beds added or subtracted, a finite if undisclosed service volume, or a specified dollar expenditure).

Desirable from all points of view, fair and reasonable standards and criteria are, as Curran (*4*) points out, the main mechanism for integrating health planning with CON. They can serve applicants' needs for objectivity, clarity, and consistency in decisions, as well as the needs of regulators and planning agencies for objective measures and strong incentives to deny unwarranted projects. In the face of a specific proposal, the tendency is to strive for an amicable solution, catering to a feeling that the applicant deserves something. If this tendency is to be offset, the competing point of view must be institutionalized into the process.

Most participants agree that well-articulated criteria for systems performance will serve their own interests, but there the consensus ends, leaving unanswered several critical questions: Who should develop the standards? What should be their characteristics? How should they be applied? Massachusetts only recently reached accord on the first question and established a committee to begin drafting quantitative standards and criteria. Understanding, acceptance, and implementation remain several steps in the future. In the meantime, the council determines need largely on the basis of qualitative criteria which are by now fairly thoroughly articulated.

The current criteria and their forerunners appear in the box. Item 4, "reasonable tools for projecting need," reflects successive revisions of the regulations and responses to the resistance occasioned by proposed quantitative standards and criteria, which arouse an almost irrational suspicion as soon as the department moves—even tentatively—to formalize them. The 1973 regulations included, in the introduction (and hence not officially part of the regulations) quantitative standards (see box). Reaction to the proposal was sufficiently negative to remove it from the next iteration, the regulations drafted in October 1974 for public review and comment prior to promulgation. That draft included increased precision in standards for determining need, but this was changed to the broad framework suggested by the reasonable tools for projecting need appearing in the final draft (see box).

Realizing at its January 23, 1975, meeting that hard standards were beyond reach for the 1975 regulations, the council tabled the issue and charged the staff to organize a statewide committee under "a" agency leadership to begin framing precise standards and criteria. Meanwhile, the reasonable tools framework has allowed the department to avoid the pitfall of casting specific quantitative standards in regulatory concrete. Formal amendment of regulations, in other than emergencies, requires months and sometimes years of administrative process. Under the reasonable tools rubric, proposed quantitative standards can be developed, used, and modified periodically, based on experience and feedback without violating the rules governing the promulgation and use of regulations. This allows flexibility while showing a good faith effort to work toward greater precision.

Without depreciating objective decision-making criteria, it may be worth noting that to tackle the problem of excess beds, any standard below the existing bed to population ratio will begin forcing a reduction. And because CON moves slowly—with years separating an initial proposal and the completion of construction and with denials simply leaving existing beds in service—considerable lag time remains for adjustments and refinements if the standards imposed begin to appear overly restrictive.

Although specific quantitative standards have virtually disappeared from the regulations, most, if not all, approvals of increases in the bed capacity of hospitals providing acute care have conformed to the suggested quantitative utilization guideline of 1.0 patient day per person per year proposed for comment by the department in the introduction to the 1973 regulations. A service-specific occupancy rate standard (88 percent occupancy in the medical and surgical services) has been applied in several determinations affecting general hospitals. None of the quantitative standards applied in the hospital sector has been appealed, although appeal would be a logical and entirely appropriate focus for dissent from the department's policy standards.

Lack of data on the capacity for institutional long-term care has frustrated the development of objective standards in that sector. Interim guidelines, adopted in May 1974, establish a ceiling in every local region of 88.9 beds per 1,000 residents aged 65 and older (the State average at the time the ceiling was imposed) with exceptions to allow flexibility for innovative proposals.

Meanwhile, the department has set out to quantify the need for institutional and community-based long-term care. A qualitative analysis, completed in spring 1973, emphasized the urgent need for community-based alternatives to long-term care and set the stage for three department-sponsored, operationally oriented research projects. The projects together seek to define the need for care (*15*) and to describe patterns of current patient placement and the factors militating for and against placements, both appropriate and inappropriate, in hospitals, nursing homes, and community settings. As the results are analyzed and melded, the three studies and the followup work ought to provide a better understanding of the long-term care system as it now operates and allow for the development of standards and of an improved, more quantitative methodology for determining the need for nursing home beds.

Sophisticated standards and criteria for ambulatory care facilities lie in the remote future. Conceivably, the current distribution of physicians and physician

equivalent visits per year (including physicians, physicians in training, and physician assistants or nurse practitioners) could be modeled against some measure of population needs. But several problems complicate this scheme: good manpower data are scarce on a State or areawide basis, ambulatory services include more than just physician visits, small but important underserved populations are difficult to identify and include in a large model, and ambiguities in definitions of "clinic" make it difficult to identify the CON applications which truly address the need for ambulatory care. The council, although firmly convinced of the need for comprehensive and accessible primary care, operates largely in the dark when determining need for clinics.

Standards to apply to judgments of facility improvement applications, particularly those involving sophisticated technology, continue to be a problem. In general, the department's approach to determining need has pragmatically concentrated largely on the macro issues, for which comparative data are available: performance characteristics (*a*) of the overall delivery system (for example, patient day to population ratios) and (*b*) of hospitals and other facilities within that system (occupancy rates and average lengths of stay).

Although building from morbidity and mortality data to a finding of bed need is generally impractical, in very special circumstances (such as renal dialysis) it is possible to look at the burden of disease (in this case, kidney disease) as the basis for determining the need for a specialized facility. The department recently drafted interim guidelines for computerized axial tomography and radiotherapy proposals, and it has initiated a study to undergird criteria for open heart surgery units. Transplantation surgery is another area which would lend itself to particular study for CON guidelines.

Conditional Certificates of Need

Initially rather aggressive and free-wheeling, the council's early experiments in attaching conditions to certificates of need occasioned heated controversy. In the program's early months, the council used conditions as a strategy to remedy glaring imbalances in the health care delivery system—for example, requiring the applicant hospital to reach an agreement with a neighboring facility on the consolidation of obstetric services. Although reasonable from a global perspective, such conditions often proved to be impracticable and frustrating for the applicant; even with the will to comply, he frequently lacked the power. The council has abandoned the experiment with broad strategic conditions and limits its stipulations to those directly bearing on the project, for example, calling for the closing down of an old wing when the replacement is built or awarding a site-specific certificate conditional on the applicant's purchase of the site.

Employing a strategy that is less direct than a condition, but that serves the same end, the council occasionally puts an applicant formally on notice, by passing a resolution when awarding a certificate of need, that the applicant will have to correct certain specified deficiencies (for example, improving planning with the community) before the council will look favorably on its future applications. The low threshhold ($100,000) on the Massachusetts CON program has had the unanticipated benefit of forcing larger providers to come through the CON process repeatedly, affording the program some continuity and its own informal enforcement mechanism.

Issues Related to Timing

A tension exists between the inevitable expense to the applicant of a delay in the project and the need for adequate time to develop and hear all relevant points of view. Because of the inflation in construction-related costs, long delays in the CON process are exceedingly costly. The statute mandates some action within 120 days of the filing date; the 1973 regulations targeted final action within 1 year; and the 1975 revision reduced that period to 8 months. However, the 1-year goal has not always been achieved; during the first 19 months, 16 of the 209 determinations were not completed within a year (*11*). The 1975 revisions of the regulations accelerate the process through a variety of administrative refinements, such as fast-track processing of routine noncontroversial proposals.

Fast-tracking is accomplished in two basic ways. "Unique applications" that are carefully and narrowly defined to exclude any proposals which would alter the scope of services or foreclose the options of another provider can be filed at any time and, after the statutorily mandated 30-day waiting period, are processed immediately. "Regular applications" which have unanimous support of approval by the applicant, the planning agency, the 10-taxpayer groups, and the department staff are administratively flagged and processed expeditiously. There is also a provision for "emergency applications," in which all procedural requirements are waived. This provision can be used only where there is a clear and present danger to health, and it has been used less than five times in the history of the program.

For regular applications, the year is divided into three 4-month periods. The department may classify as "comparable" two or more applications filed in the same period and proposing similar services to serve the same geographic area. They are then analyzed and disposed of simultaneously, not necessarily with the same outcome, but with clear articulation of reasons for differentiating them. Designed to anticipate problems attending the timing of applications, the filing period provisions succeed only partially. A dilemma still ensues when a weak applicant enters the process in advance of one that the department anticipates

within a year or two and expects to be a superior means of serving the same need. Four months is inconsequential in the life of a large project (the General Accounting Office (*16*) set the mean preconstruction planning period at 6.5 years). If circumstances force the council to approve proposals in strict chronological order, then the CON program implicitly favors large established providers with the wherewithal to put their packages together quickly. But if need can be demonstrated convincingly by a project that meets basic standards, then the council possesses no valid grounds for denial unless the "b" agency or a local consumer group argues cogently against approval, based on specific, locally generated information new to the department and the council. These groups can be particularly helpful by providing information so that the council can weigh and balance evidence on a barely adequate proposal which might otherwise slip unnoticed through the CON process. The courts have confirmed that a legislative balancing of evidence is the council's appropriate function (*11, 17*).

After finding need for a project and approving it, the department, in subsequent planning, considers this increment of need satisfied. Prolonged inactivity on an approved project is thus of concern and may warrant revocation of the certificate. The regulations state that determinations are valid for 3 years, except that those involving construction expire after 6 months if no preliminary architectural plans and specifications have been filed with the department. Revocations have affected only nursing homes. The health department has a tracking system for nursing home beds that are approved but not yet licensed which serves incidentally to flag certificates of need that have expired. No such system exists at present for general hospitals. Roughly 20 certificates of need have been revoked because of inactivity; other revocations appear imminent. The revocations to date suggest deficiencies in financial analysis because inactivity usually signals the applicant's failure to find financing. By developing an independent capacity to probe long-term financial feasibility and operating costs of proposals, the department hopes ultimately to save money by focusing attention on cost effectiveness early in the planning process.

When construction is planned in the health industry, particularly of hospitals, cost tends to be considered after a design has been chosen. Figure 5 compares this planning sequence to an ideal world with the order reversed. Through improved financial analysis, and in concert with the State rate setting commission's continuing efforts to rationalize rate structures, it should eventually be possible to bring Massachusetts around to a program-oriented design-to-cost planning model for health facilities.

Figure 5. Program planning in the construction of health facilities

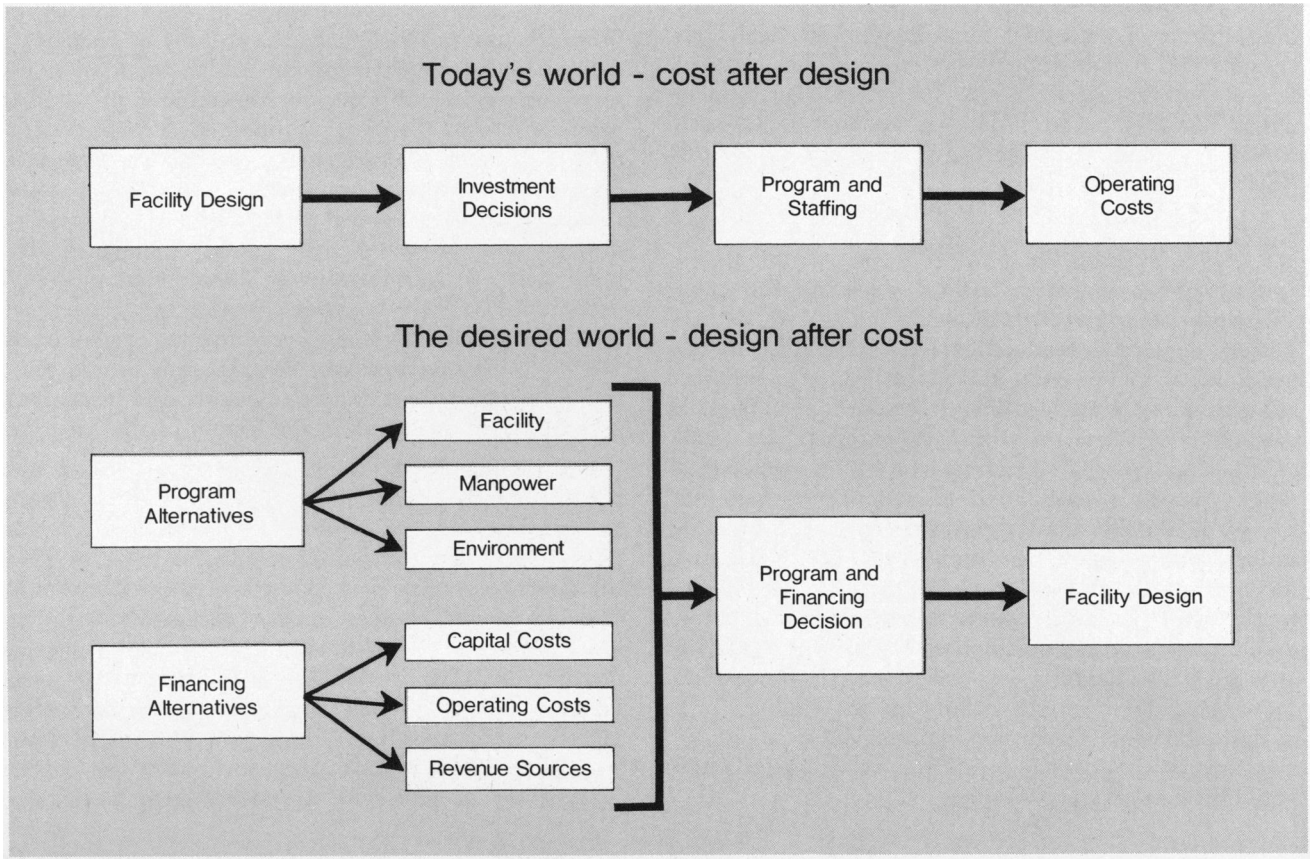
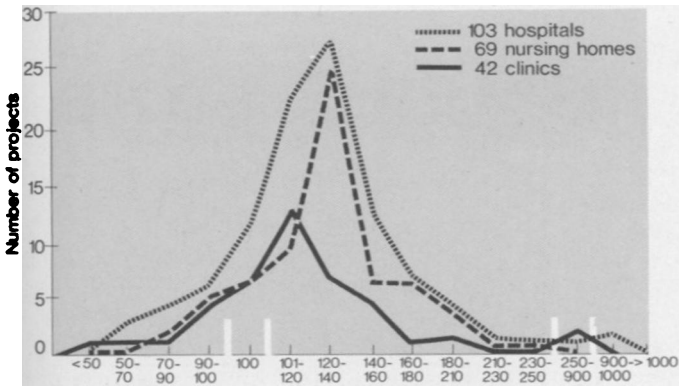


Figure 6. Cost overrun estimates involving 214 certificates of need issued after November 1971 in Massachusetts



Also related to the issue of timing was a widespread problem of cost overruns that emerged in the program's second year. Figure 6 shows the results of the preliminary analysis of 214 certificates of need issued after November 1971. Approved capital cost estimates were exceeded by 10 percent or more in 92 projects; 49 of those were running more than 26.5 percent above approved cost, with a cost overrun for all 214 projects analyzed which could finally exceed $112 million. Attributable to a combination of inflation and insufficient financial planning, the cost overruns will be monitored, but until these approved projects are completely built, the final costs will not be known.

A new cost-finding methodology has resulted from the cost overrun analyses and should prevent or at least diminish cost overruns in the future. It requires an applicant to provide a range of estimated capital costs, showing the basic components and including all past, present, and anticipated expenditures related to the project. This estimate is based on costs as of the date of approval (at today's prices) with no inflation allowance. In approving a project, the council sets an upper limit on the cost range in current dollars. An applicant whose project involves construction is then required to submit final architectural plans and specifications to the department within 9 months of the approval. Within 3 months of the department's approval of these plans, the applicant must submit firm and precise figures on anticipated capital construction costs and on the financing charge, if any. After correction as necessary for inflation since the day of application (based on the rate setting commission's inflation index), the final figure may not exceed the cost originally approved by the council. Final costs must be documented by executed financing agreements and construction contracts and, when approved, this amount becomes the cost which the department submits to the rate setting commission. Except for a 5 percent contingency allowance requiring approval and narrowly defined to cover real contingencies (such as a change in a building code or a need for longer pilings than were indicated by the initial borings taken, not including strikes, which are accounted for in the inflation factor), this council-set figure is the upper limit on the amount the applicant may spend in carrying out the project as well as the upper limit on the amount for which he can expect reimbursement. The converse however does not hold; CON approval is no guarantee of full reimbursement. In setting reimbursement rates after completion of construction, the rate setting commission may disallow reimbursement for any part of the expenditure it considers unreasonable, regardless of the project's CON status.

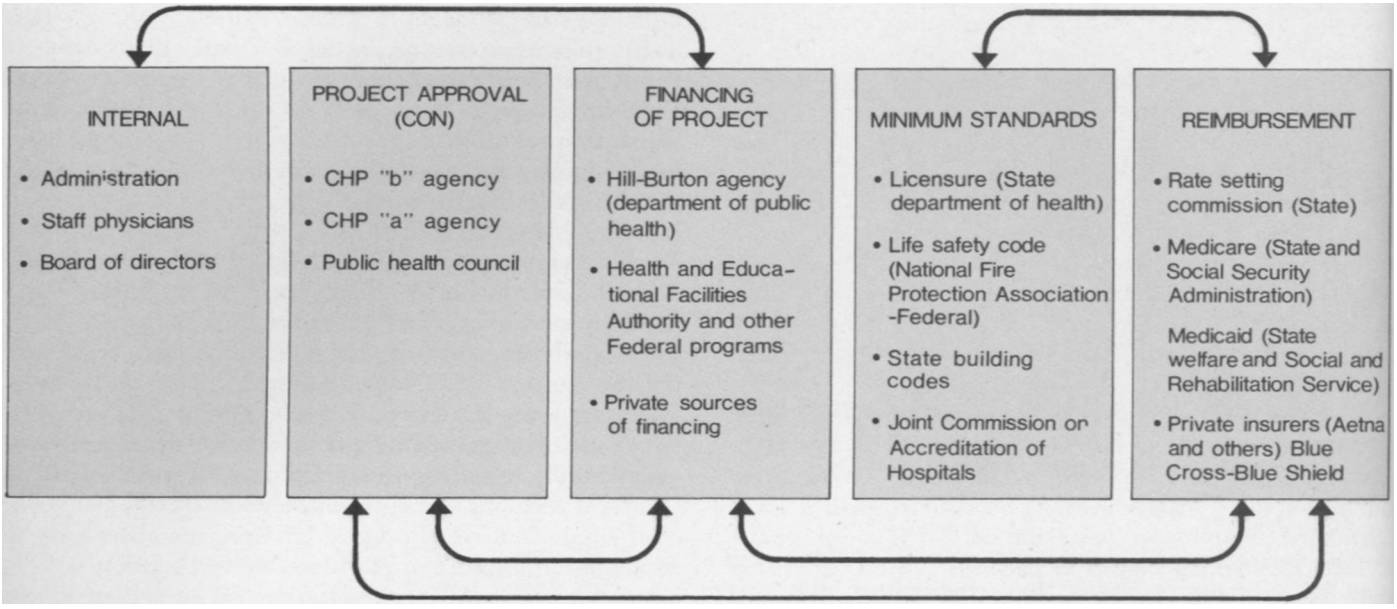
In essence, the new method permits applicants to work out program and cost details simultaneously, sequentially refining the entire picture. To simplify that picture, the inflation variable is handled only in the final analysis. Provider groups, members of the financial community, and the rate setting commission were instrumental in elaborating this process with the department. The new cost-finding procedure evolved from a rare commonality of interests; all parties stood to gain by improvements in the financial analysis of projects. Accurate cost estimates early in the planning process should insure that successful negotiation of the CON process will enhance the project's chances of obtaining financing easily. Figure 7 illustrates the discouraging array of hurdles and hoops confronting a provider wishing to expand or innovate. Any means of integrating the objectives and requirements of the programs so that they are complementary and mutually reinforcing rather than sequential, circular, or worst of all, contradictory, constitutes a step in the right direction.

Limitations of CON

Government and society expect dramatic results from certification of need laws—the language establishing them and the sweep of their objectives speak to the miracles anticipated. CON is called on to safeguard the quality, accessibility, scope, and cost-effectiveness of medical services, at present and in the long-range future, to make rational judgments on a range of subjects from architectural, engineering, financing, housekeeping, and environmental impact issues to questions of consumer participation and community need. With so much riding on the CON approach, rigorous and objective evaluation is essential. Yet the obstacles to assessment may be insurmountable; efforts to date (including our own) predominate in description and impressionism.

Elsewhere (*11*) we have described our unsatisfactory attempts at assigning a dollar value to CON cases decided during a given time period. The mere task of collecting and maintaining useful data poses a real

Figure 7. Hoops and hurdles faced by a provider who wants to expand or innovate



General observations—the present system is biased toward the known and safe. It focuses on inputs, not performance or outcomes.

challenge to an overburdened and underfunded State agency. Basic implementation—establishing the mechanics to link CON with licensure and reimbursement so that plans are approved, licenses awarded, and rates set consistently with the initial determination of need—has been far from automatic in Massachusetts. Inconsistencies have sometimes gone undetected until called to the department's attention by external parties involved in bonding and financing of projects.

These experiences have underlined the one conclusion which appears irrefutable, with or without quantitative documentation: At best CON is a limited initial mechanism, incapable of functioning adequately without strong links to licensure, financing, and utilization review. Controls governing ongoing operation and output—the fine tuning—lie beyond the purview of CON which has the authority only to react to proposals for new inputs into the system. In disposing of proposals determined to be either unneeded or inappropriate, CON frequently identifies an unmet need. But lacking adequate program and conceptual links with licensing and remuneration mechanisms, CON has no way of assuring that these real needs will be met in the future.

Public Law 93-641, with its strong endorsement of a single State agency, may bring better integration. But, to repeat our recurrent caveat, it may also possess some potential pitfalls. Consolidation will improve access to the decision-making body for the established provider with an expert legal staff, and it will tend to widen the gap between such a provider and those who are less sophisticated—consumers and fledgling providers. Moreover, whenever the State's responsibilities in reimbursement are combined with its other health regulatory duties, the danger arises that the tail (the State's cost consciousness) will wag the dog, giving regulatory decisions in general an unhealthy emphasis on minimizing the health care costs borne directly by the State, sometimes leading to decisions favoring a higher total cost to the public in order to reduce the direct cost to the State government.

Recommendations from One State's Experience

Improved linkages to other regulatory authorities. If CON is to function optimally, all participants—Federal, State, and sub-State—must appreciate the importance of continuity with other health regulatory programs, both Federal and State. Coordination with licensure and reimbursement are crucial, and it is of utmost importance that the reimbursement link take account of total cost. These links will require a data collection system for tracking projects from initial CON application to approval of plans and specifications, through construction, licensure and finally, rate setting.

Comprehensive baseline data. In addition to CON program data to serve ongoing assessment, agencies making determinations of need must have, as a minimum, the following baseline data:

1. An accurate current inventory of health care resources: locus and types, capacities, occupancy rates, numbers of admissions, average lengths of stay, by service; if possible with utilization data in sufficient detail to show, for example, for a medical or surgical service, admissions and patient days for those 65 and older

2. Patient origin data, by hospital and by city (town, zip code, or other small planning area), service specific, if possible. Massachusetts has a 1971 patient-origin study for all admissions to acute general hospitals, by both hospital and city. Most individual hospitals can supply their own more

current and service-specific patient-origin data, but we do not yet have (and badly need) service-specific patient-origin (or more accurately, hospital destination) data by city, and patient-origin data for nursing homes and other facilities

3. Population data, current and projected at least a decade into the future in sufficient detail to show at least (*a*) ages 0–14 years, (*b*) ages 65 and older, (*c*) females aged 15 to 44, and (*d*) fertility rates

4. Information on cost per unit of service

5. Volume of ambulatory care, by type of service (*a*) emergency, (*b*) specialty, and (*c*) comprehensive

6. Long-term care: a good definition of capacity, in both single and multilevel nursing homes, and in home and community care services.

Improved quantitative methods and skills. The complexities of the issues frequently involved in determining need for health facilities, the gaps and noncomparability of data, and the demands on an overextended staff result too often in hurried or erroneous analyses. Methodological improvements could take some guesswork out of the early procedural questions (for example, defining service areas, accounting for mid-week or mid-year peaking in an institution's census, and so forth) in any given analysis, leaving more time for attention to substantive issues. Practical methodologies for determining need are sorely needed, as are mechanisms for separating out policy judgments.

The agency administering the program must be adequately funded. In particular, it must have access to legal and economic expertise. Multi-State health economic service bureaus could be set up to relate to State regulatory agencies, providing the economic analysis on an ad hoc basis that few State agencies can afford to support continuously. Reviewing agencies at the sub-State level will also need adequate funding, along with access to technical assistance.

Development of performance standards and criteria. Acceptable, reasonable performance standards to be applied in determining need must be developed. These should be as objective and quantitative as possible without being overly rigid. Broad Federal guidelines or system performance indices (as promised by Public Law 93–641) could be helpful to the development process. As such, the standards must be acceptable on the State and sub-State levels. They should be developed in a manner that allows refinement and modification to accord with local variations.

Better development of alternative proposals. Expanded opportunities are needed for the formulation and presentation of alternative approaches to meeting need for service. The consumer's voice ought to be better funded outside of the constraints of the consensual model. Filing fees collected from applicants might serve as a fund from which legitimate consumer groups could draw to hire technical and legal assistance. The areawide planning agencies ought to be encouraged to work not only with applicants already in the process but also with potential applicants to foster the development of alternative and competitive proposals.

Evaluation. Continuing funding ought to be made available for long-term prospective evaluation of CON in several illustrative States and for the development and refinement of evaluation methodologies. Until we amass more valid data and better means of assessing them, we will continue stumbling in the dark when we try to pinpoint the efficacy and effect of certification of need.

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