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## **State Certificate-of-Need Programs**

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## INTRODUCTION

A major public policy response to the perceived problem of technology-induced cost inflation has been to attempt restraint of technology diffusion to hospitals (36). The prime policy instruments have been State certificate-of-need (CON) programs. CON programs vary considerably by State, but all essentially review and either approve or reject hospital equipment purchases involving technologies whose capital costs exceed some specified threshold or whose introduction to the hospital represents a significant change in service (36). NMR imaging devices, with anticipated sales prices of \$800,000 to \$2 million (see table 15 in ch. 5), are likely to come under the scrutiny of CON review in virtually every State. The potential impact of these programs and their pol-

icies on the adoption of NMR imagers is, therefore, of great interest.

This chapter is organized into four sections. The first section offers an overview of CON policies and strategies regarding the review of technology acquisition by hospitals and other providers. The second section describes the relationship of CON review to the FDA premarket approval process. Several important policy lessons drawn from the CON experience with CT scanning in the 1970s are discussed in the third section. The final section reviews the current status of CON activities that relate to NMR imaging devices.<sup>1</sup>

<sup>1</sup>Readers interested solely in CON policies regarding NMR imagers may wish to read only the last section of this chapter.

## CERTIFICATE-OF-NEED POLICIES

Although CON programs were not originally intended to constrain the diffusion of medical technology (36), they have been used for that purpose.<sup>2</sup> To the extent that individual devices had price tags exceeding the established dollar threshold for CON review, new medical technologies became subject to CON regulation. As questions arose regarding the safety, efficacy, and costs associated with new technologies, a few CON programs set out to develop technology-specific

resource and utilization standards for guiding the CON review process. The development of these standards and the evolution of CON policy toward medical technology proceeded, however, at a slow and nonuniform pace in most States (33). Complicating the problem was the fact that CON programs were being asked to control two interrelated, but distinct, aspects of technology diffusion (36): the introduction of new or innovative technology to the health care field, and the *distribution* of technology among individual health care institutions. Introduction, in this case, refers to the acceptance and adoption of innovation into clinical practice, whereas distribution implies the physical allocation of equipment among institutions (36).

Since the advent in 1976 of FDA regulation over market entry of new medical devices, the role of CON programs in controlling the "introduction" aspects of technology diffusion has diminished in importance, whereas its "distributive" role generally has been—and continues to be—its most

<sup>2</sup>Certificate-of-need programs are State programs established by State legislation and governed by State rules and regulations. To be eligible to receive Federal funds for various health programs, each State CON program must meet Federal requirements, as prescribed in national health planning legislation (Public Law 93-641, 1974; Public Law 96-79, 1979), but effective control of the regulatory process resides with the individual State. The "section 1122 programs," named after a section of the Social Security Amendments of 1972 (Public Law 92-603), are also capital expenditure review programs sanctioned by the Federal Government. These programs are administered under contract by State governments, and are empowered to withhold portions of Medicare and Medicaid reimbursement for capital from institutions that incur large capital expenditures (including those for major medical equipment) without obtaining prior approval from a designated State health planning agency.

important quality. CON agencies frequently play pivotal roles in determining which institutions may acquire new technologies. Determinations based on broad concepts of “need,” including the relative need demonstrated by competing CON applicants, are intended to ensure equitable allocation of new technology among hospitals. CON efforts to achieve distributional planning goals, however, have sometimes conflicted with program objectives involving cost containment. For example, as some observers (11) suggest, the misdirection of cost containment goals in the early years of X-ray CT scanner diffusion produced a maldistribution among hospitals that disenfranchised whole segments of the hospital industry—e.g., the municipal hospitals serving disadvantaged populations. Avoidance of this “franchising effect” is important if CON regulation is to have an even-handed impact on future diffusion of new technologies, such as NMR imaging devices.

In the past, CON programs have employed different policy orientations to address the issues associated with technology adoption and distribution (35,135). At various times, health planners have used strategies such as:

- *Pro forma denial*—denial of all CON applications for an indefinite period of time as a means of strict cost control; usually stems from serious concerns over the safety, efficacy, and cost of a technology.
- *Formalized strategy of delay*—temporary limitation of all CON applications, pending future availability of better data for CON review; often achieved through moratoria and application review deferrals.
- *Predetermined limits on diffusion*—limitation of CON approvals to specific sites or providers; often conditional on the provision of clinical data that can aid future evaluation of the technology.
- *Uncontested approval*—approval of CON applications for new technology in the absence of data on which to base sound CON decisions or in the face of statutory requirements that dictate approval unless need can be shown not to exist.

Of these four strategies, only the second and third have been used to advantage by CON agen-

cies. All, however, suffer from their reliance on the high capital-cost “trigger” that is the hallmark of CON programs, and from their inability to review technologies in the premarket stages of development (36). For these reasons, CON programs have not been successful in either controlling the introduction of new technology or assuring equitable distribution of equipment among hospitals (135). A further problem is that CON review of innovative change places health planners on less familiar ground where they lack the requisite technical, medical, and analytic skills needed to answer important questions about safety and effectiveness in the absence of FDA findings (36). *Newly* emerging technologies are especially difficult to review since the information required for assessment is usually unavailable.

At present, State CON laws generally apply to the acquisition by hospitals of medical equipment and devices that exceed specified Federal dollar thresholds:<sup>3</sup> \$400,000 for major medical equipment and \$250,000 for new institutional services (Public Law 97-35, 1981). In order to receive Federal funds for various health programs, States must comply with Federal law that requires their CON statutes to contain provisions for review of acquisitions, by anyone, of major medical equipment that will be used to provide services to hospital inpatients (182). This requirement is intended to prevent circumvention of State CON laws either by hospitals that have been denied planning agency approval for a specific technology or by physician groups seeking to acquire and install major medical equipment in a facility outside the hospital (such as a medical arts building) where technology acquisitions may otherwise escape CON review. The precise coverage policies governing CON review vary by State program, but most do not cover equipment acquisition in physicians’ offices. Only eight States (Colorado, Connecticut, Hawaii, Iowa, New Hampshire, Rhode Island, Virginia, and Wisconsin) plus the District of Columbia currently have CON laws that provide more stringent coverage of equipment acquisitions, such as in physicians’ offices, than the minimum Federal requirements (182).

<sup>3</sup>States must use these thresholds in order to comply with Federal law; they may, however, use more stringent thresholds, at their discretion.

## RELATIONSHIP OF CON REVIEW TO THE FDA PREMARKET APPROVAL PROCESS

In theory, the FDA premarket approval process should precede the CON review process, but in practice, the two often coincide. In most States, “investigational devices” are exempt from full CON review, but a notice of intent to acquire such a device for research or experimental purposes must nevertheless be filed by the hospital with the appropriate health planning agency or agencies. Thus, a hospital may acquire an investigational device without passing through formal CON review while the device is undergoing FDA review for possible premarket approval. Once FDA approval is granted to a medical device, all subsequent acquisitions by other providers must undergo CON scrutiny, provided that the acquisition involves a setting (e. g., hospital, ambulatory care center, etc. ) that is specifically covered by applicable State law. FDA premarket approval, therefore, is generally a prerequisite for widespread diffusion of a new technology but it does not necessarily guarantee broad adoption, since CON review is based on criteria that differ from those used by the FDA.

Whereas FDA review examines the safety and effectiveness of a medical device, CON review is concerned with demonstration of “need.” The definition of “need” varies greatly by State CON program and may involve such diverse factors or criteria as: consistency of the proposed project with State health plans, consistency of the project with the institutional applicant’s long-range plan, systemwide effects, financial feasibility of the proj-

ect, access to care, quality of care, availability of services and personnel, construction and architectural considerations, effects on competition, competence and character of institutional management, and selection of the best alternative means of providing the proposed service (143). FDA assurance that a device is safe and effective is not sufficient to demonstrate need for the device.

The ability of some hospitals to acquire devices in the “investigational” stage of their development without having to undergo full CON review contains potential for abuse. As was the case with CT scanners—and as we are now seeing with NMR imagers—some hospitals tend to engage in “anticipatory behavior,” i.e., they file applications for CON exemption early in the diffusion process in the hope of securing the technology before competition for the device leads to limited CON approvals. Once obtained, CON exemption bestows coveted status on a hospital relative to that of its competitors and establishes a “franchise” which, in practical terms, is not likely to be revoked by the CON program once FDA status of the device changes following premarket approval. Thus, the hospital that acquires NMR imaging as an investigational device is likely to keep the technology later when competing CON applications may be filed with the review agency. This “franchising effect” could, in the case of NMR imaging, work to the detriment of some segments of the hospital industry.

## LESSONS FROM THE EXPERIENCE WITH X-RAY CT SCANNING

Several important lessons have emerged from the CON experience with X-ray CT scanning during the 1970s, the most important of which was that slowed technological diffusion has its advantages and disadvantages. In the case of X-ray CT scanning, early CON moratoria in some areas enabled health planners and hospitals to delay critical decisions pending further information. This delay tactic allowed society to “buy time” until

better decisions regarding technology acquisition and “need” could be made. On the other hand, the inability of planners to evaluate the technology constrained its diffusion into medical practice more severely than may have been wise. The lack of available evaluative mechanisms and criteria for review made it difficult for planners to dispel the uncertainty surrounding X-ray CT scanning, thereby leading to many controversial and,

at times, seemingly arbitrary decisions on individual CON applications. The net effect was a loss of credibility by the planners, as evidence of the truly revolutionary nature of X-ray CT scanning accumulated over time. The approach of selectively controlled diffusion now being used in some States (e.g., New York, Illinois, New Jersey) with regard to NMR imaging devices is more rational, by comparison (see next section).

A second and equally important lesson was that shared CT services among hospitals proved unsatisfactory for many institutions. Practical considerations, such as access and service volume needs, worked against the basic principles of sharing, causing many hospitals to abandon their shared-service arrangements and to acquire their own X-ray CT scanners. Moreover, some hospitals found that multiple X-ray CT units were required to meet service demand, making shared services even less enticing. The same potential problem exists for the shared-service arrangements now being proposed for NMR imaging in some areas of the country.

A third lesson involved the unusual behavior exhibited by hospitals in response to the incentives created by the CON process. Anticipatory behavior of the type described earlier was by no means unexpected. In some States, hospitals were able to acquire CT scanners before CON laws took effect. In other States, problems arose when CON programs failed to recognize the inherent inequities that were created by the nature of the process itself, i.e. hospitals that obtained investigational devices became "grandfathered" once diffusion of the technology accelerated and institutions that "played by the rules" were effectively penalized for not having taken action sooner. In addition, circumvention of CON authority occurred in many States where physicians' offices were not covered by State law. The ability of private radiology groups to make large capital purchases enabled these circumventions around the CON laws to succeed.

In the case of NMR imaging, it will be difficult to control these observed behaviors. A number of hospitals have already acquired NMR imagers at significant cost, including siting and construction costs for placement of the equipment. In practical terms, it will be extremely difficult for a health planning agency to dislodge an NMR unit from an existing site. Therefore, "franchising" has already begun and is likely to continue in some areas, at least in the near term. Without CON coverage of physicians' offices and other nonhospital settings, it will be virtually impossible to control the diffusion of NMR imagers to private groups who can raise the necessary capital. Thus, continued circumvention of CON regulation is equally likely to occur.

Finally, there is the lesson regarding the clinical utilization of X-ray CT scanning. Since its early diffusion, the clinical use of X-ray CT scanning has evolved and matured. Over the years, physicians have experimented with the technology, compared it with alternative modalities, and only now are beginning to understand its optimal application— i.e., when and how to use it as a diagnostic tool. NMR imaging is more complex and requires considerable expertise and skill on the part of the physician. It will be some time before the technology's optimal clinical application will be understood even among the experts. The next few years will be a period of clinical experimentation and learning, as physicians familiarize themselves with the technology and compare it to other diagnostic imaging modalities, including X-ray CT scanning. The potential impact of NMR imaging on the future practice of medicine may prove to be as far-reaching as was the case with X-ray CT scanning in the past decade. It may, thus, be appropriate to limit diffusion of the technology to selected sites—e.g., clinical research or teaching centers or a limited number of community hospitals, where evaluation of its proper place in clinical medicine may be conducted.

## CON ACTIVITIES RELATED TO NMR IMAGING DEVICES

NMR imaging is emerging as an issue of great interest and concern to many Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs). There are indications that these agencies, which hold responsibility for local and State CON review, respectively, are beginning to see increasing CON activity related to NMR imaging. Consequently, individual agencies in several States are taking aggressive action toward convening expert task forces, developing criteria and standards for CON review, and conducting reviews of CON applications already submitted by hospitals.

As a means of gathering information on CON activities involving NMR imaging, the National Health Planning Information Center (NHPIC) sent out "Program Information Letter 83-15" on July 8, 1983, to all health planning agencies requesting that they provide information on the number of actual proposals already reviewed, the number of anticipated reviews, criteria or guidelines for review of NMR imagers, and enacted or pending State legislation governing the placement of NMR units (194).

By mid-September 1983, 27 SHPDAs and 30 HSAs had responded to the NHPIC Program Information Letter, yielding a cross-sectional view of CON activities currently under way in many States (195). Program activities relating to NMR imaging fall into three main categories: applications review, criteria or standards development, and legislation or regulations adoption.

### CON Reviews

As of September 12, 1983, 12 SHPDAs and 5 HSAs in the sample had conducted a total of 33 CON reviews for NMR imaging devices (195). SHPDAs reported review of 28 proposals with 16 approvals and HSAs reported 5 reviews with 3 approvals. The total of 19 approvals excludes waivers and exemptions for research applications. In addition, the agencies reported the receipt of 43 letters of intent or new proposals: 18 by SHPDAs and 25 by HSAs (195). Capsule summaries of selected CON reviews appear below.

### Missouri

Missouri became the first State to approve NMR imaging in a nonresearch, nonuniversity-affiliated hospital setting when its CON agency, the Health Facilities Review Board, approved the applications of two community hospitals located in Columbia (64). The review board made these controversial decisions despite SHPDA recommendations to the contrary (64). The review board also rejected SHPDA recommendations for limited diffusion of NMR imaging to only university hospital settings and for the formation of a task force to develop criteria and standards for CON review of the technology (99).

The two hospitals receiving CON approval are Columbia Regional Hospital, a 301-bed facility that is part of the Lifemark investor-owned hospital chain, and Boone Hospital Center, a county-owned, nonprofit facility with 344 beds (64).

### Illinois

In the absence of NMR criteria for CON review, the Illinois CON agency (the Health Facilities Planning Board) has invoked the technologically innovative equipment clause of the State CON law to limit the diffusion of NMR imaging to medical school affiliated hospitals (see later discussion under legislation or regulations). As of August 1983, two hospitals affiliated with medical schools (Rush-Presbyterian-St. Luke's Medical Center in Chicago, and St. Francis' Hospital in Peoria) had applied for and received CON approval for NMR imaging devices (72).

### Nebraska

Beginning in late 1982 and early 1983, the State CON agency received multiple applications for NMR from individual hospitals in Omaha. In an effort to encourage cooperative planning, the State agency announced in the spring of 1983 that it would "batch" NMR applications for simultaneous review (205). Three private, nonprofit hospitals (Nebraska Methodist, Archbishop Bergan Mercy, and Children's Hospitals) responded by forming a private corporation, NMR Inc., which

submitted a single CON application to place an NMR imager in a freestanding facility where all three hospitals would share access. In July 1983, NMR Inc. received CON approval for the acquisition of a superconducting NMR system. Also receiving CON approval in July for NMR imaging was the University of Nebraska Hospital, which has referral agreements with two other facilities, Omaha Veterans' Hospital and Bishop Clarkson Hospital (205). One other CON application for NMR was reviewed and recommended for denial; the hospital subsequently withdrew the application and is now seeking a cooperative arrangement with a second hospital (205).

### Kentucky

Albert B. Chandler Hospital, a teaching affiliate of the University of Kentucky, currently has an NMR imaging unit, which was granted exemption from CON review as a research/experimental device (62). In May 1983, the State CON agency reviewed and disapproved an application for NMR from Audubon Hospital, a Louisville facility that is part of the Humana investor-owned hospital chain. In making its decision, the SHPDA invoked the Kentucky State Health Plan, signed by the Governor, which states that NMR technology ". . . shall be considered a tertiary level service and approval of one unit will be considered for each of the two designated tertiary centers"<sup>4</sup> in the State (195). The CON decision was appealed by the hospital and granted reconsideration by the SHPDA (62). Since Humana leases and manages the tertiary center in Louisville (Humana Hospital-University), the corporation argued that placement of an NMR imager at Audubon Hospital (a Humana-owned facility) would still permit patients from the university hospital to have access to the technology. Following a public hearing, Audubon Hospital's application was approved by the SHPDA.

The University of Kentucky's Albert B. Chandler Hospital has applied for CON approval to use its previously installed NMR unit for clinical, as well as research, purposes.

<sup>4</sup>"Centers" refers to the two university hospitals in the state: Albert B. Chandler Hospital in Lexington and Humana Hospital-University in Louisville (62).

Other jurisdictions in which CON applications for NMR have been reviewed include: SHPDAs in Georgia, Tennessee, Texas, Ohio, Iowa, Arizona, Kansas, and California; and HSAs in Middle Tennessee, New York City, North Central Georgia, Chicago, and Southeast Kansas.

### CON Criteria or Standards Development

As of September 12, 1983, 10 health planning agencies (HSAs and SHPDAs) had reported to the National Health Planning Information Center that they had established NMR-specific review criteria or guidelines. An additional 15 agencies are in the process of developing review criteria (195). Two of these reported that they were using CON review criteria or standards for CT scanners as the basis for their efforts in NMR imaging (158). Several agencies have also formed or are beginning to form expert task forces or advisory panels. A brief summary of current State and local efforts in this regard appears below.

#### Nebraska

The Statewide Health Coordinating Council (SHCC) in April 1983 authorized the formation of a 12-member Task Force on New Developments in Diagnostic Radiology to develop NMR guidelines. The Task Force consists of seven radiologists, one internist, one neurosurgeon, and one consumer member of the SHCC (205). In September 1983, the Task Force submitted for review a set of draft guidelines for NMR scanners. The SHCC also created a separate Task Force on New Technological Developments, which prepared and submitted in September 1983 draft guidelines for review of emerging technologies.

#### Massachusetts

The SHPDA in Massachusetts is working with the State CON agency (the Determination of Need program) to develop criteria and guidelines for CON review of NMR (28). An Advisory Committee on NMR is being formed, with representatives drawn from the State Rate Setting Commission, the hospital industry, the professional medical societies, and consumers. It is anticipated that the State may move toward limited diffusion of NMR imaging during an initial research/experimentation phase (28).

In an apparently independent effort, the Health Planning Council for Greater Boston (the State's largest HSA) developed proposed guidelines for NMR, which were expected to be adopted in final form in December 1983 (79). The proposed guidelines would allow NMR units to be placed in clinical, nonteaching settings under certain conditions (79).

### Georgia

The Georgia SHPDA, with the aid of medical specialty societies and other professional groups, has convened a "blue ribbon committee" of experts to develop NMR-specific criteria and guidelines for review (75). The committee, which is composed of radiologists, nuclear medicine specialists, internists, and hospital administrators, was expected to release a draft final report in the fall of 1983. The anticipated recommendations are likely to urge caution, with NMR diffusion temporarily restricted to two medical schools pending FDA approval and the articulation of reimbursement policies for NMR (75).

### Oklahoma

The State CON agency in Oklahoma is now in the process of assembling a Select Committee on Technology to recommend criteria and standards for NMR (25). Two avenues that will likely be explored are the limited diffusion strategy of the Illinois CON program and the group application/shared-service model encouraged by the Nebraska CON program (see the earlier discussions of both States' experiences with CON reviews).

In addition to these CON programs, other agencies involved in either task force development or criteria/standards development include SHPDAs in the District of Columbia, New Jersey, North Carolina, Illinois, Ohio, Maryland, Hawaii, Florida, and Pennsylvania, and HSAs in Southeastern Massachusetts, Central New Jersey, Eastern Virginia, North Central Georgia, Western Michigan, Central Arizona, and Northwest Oregon (69,134,172,195). Several other agencies have developed either NMR plans (Newark HSA, Southeast Kansas HSA) or position papers (Southeastern Pennsylvania HSA, Southwestern Pennsylvania

HSA). Developmental activities of this nature are expected to continue and expand in other areas of the Nation (13).

The American College of Radiology (ACR), a medical specialty society, has been contacted by many State CON agencies requesting information on NMR imaging. In response to these requests, the ACR (through its Commission on NMR, Subcommittee on Government Relations) prepared a document, "Guidelines for Preparation of CON Applications," intended to assist State CON agencies in performing reviews of NMR-related CON applications.

### State CON Legislation/Regulations

During 1983, significant developments occurred in several States regarding CON legislation or regulations that affect the review of NMR imaging devices. A sampling of major developments follows.

#### New York

The New York State Hospital Review and Planning Council, the CON body in the State, drafted regulations that call for a 2-year demonstration period in which NMR imaging will be restricted to a select number of hospitals (127). During this period, data on the technology's safety, efficacy, and cost effectiveness will be gathered and analyzed. Upon completion of the demonstration, a determination of need will be made and, provided that neither cost effectiveness nor quality of care is at issue, all participants in the demonstration as well as any other hospitals in the State may then apply for CON approval. The proposed regulations were expected to be reviewed and approved by the council in the fall of 1983. The council made the decision in April 1984 to permit placement of NMR imagers in no more than 13 teaching hospitals during the demonstration period (19).

The application for NMR submitted by New York Hospital is generally credited with having precipitated this regulatory process (127). The hospital's application was approved with the understanding that it could not receive reimbursement for NMR unless it was selected to partici-

pate in the planned demonstration. The Major Medical Equipment Committee of the Council will commence development of NMR review criteria or standards once the demonstration gets under way and preliminary data are produced.

### Illinois

As alluded to earlier in the discussion of CON reviews, the Illinois Department of Public Health and the Illinois Health Facilities Planning Board adopted regulations on March 1, 1983, that set forth specific "Standards and Criteria for Review of Applications for Permit for Technologically Innovative Equipment or Innovative Programs" (195). These regulations stipulate that any such equipment or programs must be restricted to only medical school settings until FDA premarket approval for the technology is granted and CON guidelines or criteria for review have been established. This effectively limits NMR diffusion to only 11 hospitals in the State (one hospital per medical school). NMR imaging is among the first technologies to be regulated under these rules (72).

### District of Columbia

In September 1982, the CON law in the District of Columbia was amended to permit the designated CON agency the right to declare a 180-day "holding period" on the review of any new technology whose safety, efficacy, and clinical use are not clearly understood or are in question (134). The CON agency has, since that time, drafted general criteria and standards for CON review. Two clauses specifically relate to new technology. One requires that applicants demonstrate to the SHPDA director's satisfaction that the technology is beneficial in controlled trials. The second clause requires applicants to demonstrate need for technology acquisition relative to actual or potential need for such technology at other institutions in the District. The agency received a CON application for NMR imaging from an area hospital in February 1984 and immediately invoked the 180-day moratorium provision pending development of review criteria (203). The agency has convened a technical advisory panel and expected to develop criteria and standards for review of NMR imagers by August 1984.

### New Jersey

In November 1983, the New Jersey SHCC approved a proposal that would restrict CON approval of NMR imagers to no more than four sites over an evaluation period of 2 years (69). In selecting the four sites, preference will be given to the State's 16 major teaching hospitals. Data gathered from the four installations would be used to guide decisionmaking on future NMR diffusion in New Jersey. In an unprecedented move, the State Commissioner of Health asserted that these new NMR regulations would apply to physicians' offices as well as other health care facilities (69). Under present New Jersey law, physicians in private practice are exempt from CON review (195). However, the State Department of Health views the purchase of NMR by physicians' groups as going "far beyond the private practice of medicine" (69).

### Utah

The CON law in Utah was amended in May 1983 to *exempt* all medical equipment from CON review (74). NMR imaging devices, therefore, will not be subject to CON review in Utah, as the State appears to be pursuing a strategy of uncontested approval for all medical equipment purchases.

### California

The State of California has also passed legislation that eliminates the dollar thresholds for CON review of major medical equipment purchases (201). As in Utah, NMR imaging devices will not be subject to CON review in California.

### Future Prospects

The general consensus among health planners and CON agency staff members who were contacted for this study was that the level of CON activity related to NMR imaging is likely to increase dramatically over the next year. Once HCFA renders a policy decision regarding Medicare coverage, planners expect to see a rapid increase in the number of CON applications filed by hospitals around the Nation.<sup>5</sup> In anticipation

<sup>5</sup>Several proposals are now before the Congress that would raise the CON thresholds for equipment review to \$1 million or higher. If such legislation was enacted in the next few months, some States might follow suit and amend their statutes, effectively exempting the less expensive NMR systems from CON review.

of this onslaught of paperwork, CON agencies at both State and local levels in the national health planning structure are continuing to push forward in the creation of special task forces and in the development of criteria and standards for CON review.

Of the four strategies previously described for CON treatment of medical technologies, at least three appear to be operating with respect to NMR imaging. The New York, Illinois, Ohio, Kentucky, and New Jersey SHPDAs; and the Eastern Virginia HSA all appear to be employing predetermined limits on diffusion, whereas the Southeast Kansas HSA and the District of Columbia SHPDA have adopted moratoria on NMR pending further study and planning (38,69,117,195). Nebraska, by contrast, is encouraging shared-service arrangements. Both Utah and California, at this time, appear to be using a strategy of uncontested approval. No CON program, on the other hand, has adopted a policy of pro forma denial.

NMR imaging is likely to differ from the CT experience in several ways. First, and foremost,

are the site considerations that are unique to NMR imaging. Unlike the placement of CT scanners, NMR installation is costly and is likely to have considerable impact both on hospital plant configuration and on the organization of staff. NMR placement can be disruptive to the hospital, making internal management of the technology and its use far more difficult than was (or is) the case with CT. Shared service arrangements among hospitals may prove fragile, owing to the fact that host institutions may experience difficulty in rationing the use of NMR imaging among participants. Utilization of NMR units may increase tremendously as physicians discover new clinical applications and perform "sequential scanning." Should NMR imaging come to be used in this way, hospital administrators will find it difficult to ration NMR use among medical staff members, let alone among other hospitals. Interspecialty disputes over the use of NMR imaging may further cloud the issues of appropriate utilization and rationing.