

# 6.

## Regulation of the Providers of Medical Device Devices

For the general run of consumer goods the buyer is necessarily an amateur  
while the seller is a professional

—*Joan Robinson*

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# Regulation of the Providers of Medical Devices

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## INTRODUCTION

Regulation in health care has developed because of certain conditions that set the health care field apart from many others. Large segments of the American public do not have sufficient medical knowledge to make informed decisions about their health care. To a significant extent, therefore, especially in the case of sophisticated procedures and unusual medical conditions, patients must rely on the judgment of physicians or other health care professionals. Furthermore, as described in chapter 3, the system of third-party financing for medical care that has evolved in this country has fostered the uncritical adoption and sometimes excessive use of medical technologies, including medical devices. Such adoption and use, in turn, have contributed to a rapid rate of increase in Federal expenditures under programs such as Medicare and Medicaid and in national health care expenditures generally.

Chapter 5 discussed the Food and Drug Administration's regulation of drug and device manufacturers to protect the public from unsafe and ineffective drugs and medical devices. This chapter examines regulations pertaining to the health care institutions and individuals—i.e., hospitals, nursing homes, home health agencies, ambulatory surgi-

cal centers, clinical laboratories, and others—that provide or use major medical equipment, such as computed tomography (CT) scanners, or smaller devices, such as sutures or splints.

Various Federal and State regulatory programs affect the providers of medical devices. As noted in the discussion that follows, regulation of health care providers has been undertaken with several objectives in mind:

- that people receive care of acceptable quality,
- that rising expenditures on health care are controlled, and
- that the distribution of medical facilities is equitable.

This chapter analyzes the impact of Federal and State regulation of providers on adoption and use of medical devices in specific health care delivery sites. It also discusses interactions among the regulations and proposed changes. Although decisions to adopt and use medical devices are typically made by physicians, most of the regulations discussed in this chapter affect physicians only indirectly.

## FEDERAL REGULATION OF PROVIDERS

At the Federal level, providers of services to Medicare beneficiaries are regulated through conditions of participation, section 1122 of the Social Security Act, and professional standards review organizations (PSROs) (currently being replaced by the utilization and quality control peer review organizations, PROS). Providers are also regulated under State laws required by the Federal health planning program.

### Federal Regulation of Providers Under Medicare

Designers of the Medicare program wanted to ensure that the Federal Government paid for good quality care for elderly and disabled people eligible for benefits under this program (107), and conditions of participation for providers were adopted at the outset of the program to attain a

satisfactory level of quality. As the program was implemented and costs rose, cost containment also became an issue. Thus, in the Social Security Amendments of 1972 (Public Law 92-603), both to help ensure beneficiaries' access to quality medical care and to help contain costs, Congress created the PSRO program and added section 1122 to the Social Security Act. Along with conditions of participation, PSRO review of the utilization and quality of services provided to Medicare beneficiaries and section 1122 review of capital expenditures are described further below.

### Conditions of Participation

Conditions of participation are requirements that must be met by hospitals and other providers in order to receive payment for treating Medicare or Medicaid patients. The purpose of the conditions is to assure a basic level of quality of the medical care for which the Federal Government pays (107). The conditions of participation for hospitals are similar to the voluntary standards promulgated by the Joint Commission on Accreditation of Hospitals (JCAH) (see box L) or the American Osteopathic Association. About 5,200 hospitals accredited by JCAH or the American Osteopathic Association are automatically considered in compliance with Medicare quality standards. However, an additional 1,495 hospitals are not accredited by either of these organizations but do participate in Medicare or Medicaid (315).

Some conditions of participation for providers list specific medical devices whose availability is required. The lists of devices in conditions of participation are generally not extensive or exhaustive, but instead allow providers flexibility in deciding which services to make available. Hospital operating suites, for example, must have the following equipment available: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, thoracotomy set, and tracheotomy set (42 CFR 405.1031 (a) (11)). Freestanding ambulatory surgical centers must provide laboratory and radiologic services that include, but are not limited to, such medical devices as surgical dressings, splints, casts, appliances, materials for anesthesia, and diagnostic or therapeutic services directly related

to the provision of surgical procedures (42 CFR 416.46 (c)).

The conditions of participation have not undergone any substantial revision since Medicare began operating in 1966. Revisions proposed by the Department of Health and Human Services (DHHS) in January 1983 would make the conditions of participation for hospitals less prescriptive, allowing hospital medical staff and administrations greater flexibility in the provision of inpatient medical care. Statutory requirements are still included, but the proposed changes "... are intended to simplify and clarify requirements, to focus on patient care, to emphasize outcome rather than the means used to achieve those ends, to promote cost containment while maintaining quality care, and to achieve more effective compliance with Federal requirements" (315). Beneficiary and labor groups have protested the new regulations, and the Secretary of Health and Human Services has delayed publication of the final rules by returning them to the Health Care Financing Administration (HCFA) (452).

Many of the existing conditions of participation for providers specify educational and experience requirements for personnel, similar to JCAH standards. Stringent personnel requirements can have several effects on the diffusion of medical devices. Requirements for highly trained (and therefore often expensive) personnel to perform certain tasks give providers such as clinical laboratories incentives to purchase capital equipment that reduces the number of personnel required to perform the task (provided the available personnel are already being used efficiently) (120,227). If such capital equipment is expensive, hospitals and facilities that provide services to inpatients must comply with section 1122 of the Social Security Act and State certificate-of-need (CON) regulatory programs required by the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). These Federal and State programs, discussed further below, were responses by policymakers to several problems: the duplication of facilities and services, which contributed to the high cost of health care; access to health care, especially as it pertained to the maldistribution of services; and the high cost of medical care

### Box CommL.—Joint Accreditation Hospitals (JCAH)

The standards for that were adopted for the Medicare program in the Social Security Act of 1965 were based on the 1965 standards for quality by JCAH. Congress had recognized the need for quality assurance for the medical care to be paid through and Medicaid, and the JCAH standards were and acceptable to medical professionals and the public (107).

JCAH was an outgrowth of the hospital accreditation program initiated by the American College of Surgeons in 1918 to ensure that hospitals had the necessary equipment and supplies for good quality patient care. In 1951, the financial burden of standard setting and facility surveying proved too great for the American College of Surgeons. JCAH was founded that year by joining the American College of Surgeons, American College of Physicians, American Hospital Association, American Medical Association, and the Canadian Medical Association for the purpose of accrediting hospitals. The Canadian Medical Association withdrew in 1959, when it formed the Canadian Council on Hospital Accreditation. The American Dental Association joined JCAH as a corporate member in 1979.

Hospitals must be in substantial compliance with JCAH standards in order to be accredited for a period of 3 years. They must demonstrate through a survey process that they meet the applicable standards, either through the hospital's own facilities and staff or by sharing some outside services. Shared services may be contracted for with another accredited hospital or an agency that maintains the level of performance required by JCAH standards. Each hospital must agree to conduct an interim self-survey at the midpoint between its JCAH surveys.

The 1965 JCAH standards adopted by Medicare for its conditions of participation included the requirement of urinalysis and hemoglobin or hematocrit tests for all patients upon admission. This requirement contributed to the overuse of tests and the medical devices involved in performing them. In the early 1970s, this standard was eliminated, and in 1979, JCAH reinforced the principle of "no standing tests" common to its hospitals (222).

In general, JCAH standards do not specify medical devices that must be available in hospitals for rather, the medical staffs at the hospitals are left to decide about particular medical devices that will assist in the provision of quality care. In certain instances, such as the emergency service/department, patient safety requirements specify medical devices and their maintenance. For example, the 1983 *Accreditation Manual for Hospitals* specifies in Standard II for Functional Safety and Sanitation:

Methods and frequency of testing, and verification of performance —specifications and use-specifications, for all electrical and electronic patient care equipment, based upon established safety requirements, performance criteria, and manufacturers' claims. Such testing and verification shall apply to both fixed and mobile equipment, with particular emphasis on life-support such as respirators, defibrillators, physiologic monitoring systems, infant incubators and warmers, as well as devices with a high hazard potential such as electro-surgical equipment . . .

Standard setting process in JCAH, and input is sought from specialty organizations, other experts in applicable areas, and relevant government agencies (such as the Health Care Financing Administration, Medicare). JCAH develops standards in response to identified needs to measure quality of a service or a particular aspect of care. New or revised standards may be needed when there are ". . . innovations in techniques, advancements in knowledge, changes in governmental regulations, or the demand by consumers for accountability. . . ." (176). The use of experimental devices, unlike experimental drugs which are addressed by JCAH, is not covered by a specific standard (222).

The assumption underlying the voluntary JCAH standards is that a necessary but not sufficient condition for good quality medical care is the availability of certain facilities, including medical technologies and staff. JCAH strives for the following characteristics for its standards: 1) validity, meaning that the standards relate to quality of care; 2) encouragement of excellence within available resources; 3) meaning that the standards have been met by an existing hospital; and 4) measurability (176). The effect of JCAH standards on the quality of care delivered in hospitals is anecdotal. Quality has improved, but a direct causal relationship has not been established.

borne by Medicare and Medicaid. The interaction of various Federal and State regulations for independent clinical laboratories is described in box M.

The effects of Medicare conditions of participation on the adoption and use of medical devices are unclear. Initially, there was an impetus for the Federal Government to approve as many hospital beds as possible so that the Medicare guarantee of access to medical care for elderly people would be operational on the first day of the program's implementation (7,107). In some cases, hospitals that had not previously been accredited because of failure to meet "contemporary standards of technology, staffing, and medical practice" were certified by Medicare as "in substantial compliance" (107). The incentives for facilities to achieve full compliance were weak, because hospitals with conditional certification were paid on the same basis as those in full compliance.

Since Medicare conditions of participation for hospitals were based on JCAH accreditation standards, any evidence on effects of the voluntary JCAH standards would apply to these conditions as well. Unfortunately, there is little evidence that accreditation has had an impact on the quality of care in hospitals or on the adoption of new medical technologies (227). Whether or not the conditions of participation affect the adoption and use of specific medical devices is impossible to prove because of the general lack of specificity regarding medical devices in most of the conditions of participation (and in the JCAH standards). Data sources for comparisons also lack specificity regarding medical equipment.

Medicare's diagnosis related group (DRG) based prospective payment system for hospitals, which was mandated by the Social Security Amendments of 1983 (Public Law 98-21) and is currently being implemented (see ch. 3), changes the environment for Medicare-based regulatory programs. Medicare's DRG hospital payment system may enhance the importance of conditions of participation for quality of care. The same law that mandated DRG payment also added a new "condition of payment": In order to be paid for treating Medicare patients, hospitals must contract with PROS (see "Utilization and Quality Review Programs" section below).

## Utilization and Quality Review Programs

Utilization review programs in hospitals have been a condition of participation for hospitals participating in Medicare since the program's inception in 1966. In the original Medicare legislation, hospitals were required to have periodic reviews of the medical necessity of admissions, extended stays, and professional services rendered (42 CFR 405.1035 (a)). The purpose of these reviews was to help contain costs and to ensure quality of care. Medical device use was to be evaluated in connection with the review of professional services.

Congress mandated the PSRO program in the Social Security Amendments of 1972 (Public Law 92-603) to carry out these utilization and quality review responsibilities. PSROs, which as noted above are currently being replaced by PROS, are areawide groupings of practicing physicians designated by DHHS to review services provided to Medicare and Medicaid beneficiaries. Their purpose has been to ensure that the services Medicare and Medicaid pay for are: 1) medically necessary, 2) of a quality that meets locally determined professional standards, and 3) provided at the most economical level consistent with quality of care. Thus, the two objectives of the PSRO program have been quality assurance and cost containment (345).

In theory, PSROs were to accomplish these goals by conducting three types of evaluations in inpatient hospital settings, long-term care facilities, and ambulatory care settings:

- utilization reviews (e.g., reviews of the length of stay and medical necessity of admissions);
- medical care evaluations or quality review studies (e.g., audits of patient records to monitor the appropriateness of tests, drugs, and procedures administered to patients); and
- profile analyses (e.g., reviews of hospital physicians' patterns of care to identify potential problems).

in practice, PSROs have tended to emphasize utilization reviews in inpatient settings, focusing on the identification of high hospital admission rates and lengths of stay. One of the reasons is that identifying high usage of hospital care has proved easier than identifying underuse of hos-

**Box M.—Interaction of Regulations for Clinical Laboratories That Test Ambulatory Patients<sup>1</sup>**

Three general types of clinical laboratories perform tests for ambulatory patients: hospital-based, independent, and physician office laboratories. Regulations for each type depend on the States in which the laboratories are located and the patients whom they serve. Standards and regulations have been set by voluntary associations, such as the College of American Pathologists and the Joint Commission on Accreditation of Hospitals (JCAH), and by Federal and State Government agencies.

At the Federal level, there are regulations under Medicare and under the Clinical Laboratory Improvement Act (CLIA). CLIA was administered by the Centers for Disease Control until 1979, but since then has been administered, along with Medicare, by the Health Care Financing Administration (HCFA).

Laboratories that can be paid for tests on Medicare (and, usually, Medicaid) patients must meet the standards specified in the Medicare conditions of participation for hospitals or conditions for coverage of services of independent laboratories. Hospital laboratories that have been accredited by JCAH or the American Osteopathic Association are deemed to be in compliance with the Medicare conditions of participation.

Laboratories that conduct interstate business must meet the requirements of CLIA or be accredited by an association or licensed by a State with more stringent rules. Currently, only interstate laboratories that meet New York State licensure and the highest accreditation of the College of American Pathologists are exempt from CLIA requirements. Physician office laboratories are generally exempt from Federal regulations unless they annually accept more than 100 specimens on referral from other physicians.

Federal performance standards fall into three categories. First and most costly are educational and experience requirements for laboratory personnel. Personnel requirements under Medicare and CLIA are stricter for interstate and independent laboratories than for intrastate hospital laboratories. (The two Federal programs are almost identical now that they are both administered by HCFA.) Second, all interstate licensed laboratories and all Medicare-certified laboratories must comply with quality control requirements. Third, Federal regulations require external validation of a laboratory's performance via participation in proficiency testing programs.

In addition to complying with the comprehensive, detailed Federal regulations, laboratories in most States must comply with State licensing regulations. Hospital laboratories in 39 States are licensed through hospital licensing or separate laboratory licensing programs. In nine other States, there are requirements for specific tests performed in the hospital laboratories. Independent laboratories in 26 States must meet licensing requirements; and in 15 other States, they must meet requirements for performance of specific tests.

Physician office laboratories are licensed in Nevada, New Jersey, and Pennsylvania, where they must comply with specific regulations. In California, physician office laboratories that perform tests for Medi-Cal patients are regulated. Other States regulate physician office laboratories, depending on one or more of the following factors: 1) if there is more than a specified number of physicians; 2) if the laboratory accepts specimens on referral; 3) if the testing is done by a non-physician; or 4) if certain specialized tests are performed. Some States require all physician office laboratories to participate in proficiency testing programs.

<sup>1</sup>Based on a paper prepared for OTA by Foster (120).

pital care or specific medical technologies. Furthermore, from the standpoint of reducing Medicare costs, reducing overutilization of hospital admissions and lengths of stay is clearly important. Reducing overutilization of hospital care is likely to be more cost saving than reducing underutilization, although it could be argued that from the standpoint of quality assurance, it is also important to consider the latter.

PSRO utilization reviews in hospitals, although not focused on particular drugs, devices, or medical procedures, may nevertheless have indirectly affected the utilization of specific medical devices. Quite conceivably, changes in hospital admission rates and lengths of stay may have indirectly affected the use of diagnostic tests and other device-based procedures routinely used for hospital patients.

Like PSRO utilization reviews, most medical care evaluations and profile analyses have been conducted by PSROs in inpatient hospital settings. Unlike utilization reviews, however, some medical care evaluations have been directly focused on the appropriate use (including underutilization) of specific medical devices.

Thus far, evidence on the effectiveness of review programs has been mixed. Analysts considering benefits of review programs have examined both cost savings and contribution to quality assurance. Evidence is inconclusive that utilization review programs have achieved net cost savings when reductions in length of stay and admissions are considered along with the costs of the review program (50,57,325,326,334,395,397,409,411). Evidence that review programs have improved quality of care is limited but suggestive (57,395).

No specific evidence of the effects of PSRO or hospital review programs on the adoption and use of medical devices has been reported, although a study of one hospital showed that length of stay and average charges per patient (probably related to medical device use) generally decreased following institution of PSRO review. The decrease, however, did not result in savings to Medicare and Medicaid because of an increase in hospital admission rates also attributed to PSRO review (455).

As noted earlier, the Social Security Amendments of 1983 added as a new "condition of payment" for hospitals treating Medicare patients the requirement that hospitals contract with PROS. PROS have responsibility for monitoring ancillary service use and hospital discharges that result in quick readmissions, because Congress recognized the financial incentives under DRG prospective payment to use as few ancillary services (including those involving medical devices) as possible, to discharge Medicare patients as quickly as possible, and to admit as many cases as possible.

PROs, the replacements for the PSROs, are contract organizations that must affirm their utilization review and quality assurance objectives, as well as define their specific plans on how to attain these objectives, in their contracts with HCFA. Medical devices will be subject to evaluation under the PRO function to review the completeness, adequacy, and quality of care to hospital inpatients. A specific requirement in the scope of work for PROS is to monitor cardiac pacemaker implantations and reimplantations for unnecessary procedures (407).

### **Section 1122 Capital Expenditure Review**

Section 1122 of the Social Security Act and State CON laws required by the National Health Planning and Resources Development Act (see "Federal Health Planning Regulations" and "State Certificate-of-Need Laws" sections below) potentially could have the most direct effect on medical devices of any of the provider regulations discussed in this chapter. Congress mandated section 1122 capital expenditure review in the Social Security Amendments of 1972 (Public Law 92-603). The purpose of section 1122 review is to ensure that Federal funds for Medicare, Medicaid, and the Maternal and Child Health and Crippled Children's Services programs are not used to support unnecessary capital expenditures by health care facilities. Section 1122 of the Social Security Act authorized the Secretary of Health, Education, and Welfare (now Health and Human Services) to enter into contracts with States that were willing and able to do so. Under these contracts, a State or State health planning agency would review expensive capital expenditures, and the Sec-

retary could withhold reimbursement for expenditures that were disapproved.

Under section 1122, capital expenditures by specified health facilities that exceed a certain threshold—initially \$100,000, currently \$600,000—are subject to review by a State or State planning agencies. Also subject to section 1122 review are changes in numbers of beds or substantial changes in the services offered in medical care facilities. As of 1983, only 15 States had contracts with DHHS to conduct section 1122 capital expenditure reviews.

Section 1122 currently applies to hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers, intermediate care facilities, and ambulatory surgery centers. Medicare and Medicaid reimbursement to these facilities can be denied only for unapproved *capital expenditures* (i. e., expenses related to depreciation, interest on borrowed funds, or, in the case of proprietary facilities, return on equity for capital equipment or construction). Reimbursement for operating expenses associated with unapproved capital equipment or construction is not affected.

Because of the high threshold for section 1122 review and the State-based decisionmaking process provided for in the law, the effect of section 1122 provider regulation on medical devices is probably similar to that of the State CON programs required by the National Health Planning and Resources Development Act of 1974 (see section on “State Certificate-of-Need Laws” below). Only a few devices—e. g., CT scanning and nuclear magnetic resonance (NMR) equipment—exceed the threshold for section 1122 review. Thus, most purchases of medical devices by the facilities to which section 1122 applies can be made without section 1122 review.

## Federal Health Planning Regulations

Bringing together several strands of previous legislation, the National Health Planning and Resources Development Act of 1974 (Public Law 93-641) outlined national health priorities and replaced the existing network of voluntary agencies with a system of about 200 local health sys-

tems agencies and State health planning and development agencies. The purpose of this act and related health planning legislation was to centralize decisionmaking at the State level in order to rationalize resource allocation and control escalating rates of cost increases.

The 1974 law called for the provision of greater authority to State and local planning agencies over hospital investments. The law required State health planning agencies to review CON and section 1122 applications from medical facilities regarding capital investments. State planning agencies have the responsibility of determining the numbers and types of facilities and services needed by their populations. State Health Plans to accomplish the equitable distribution of these health care services are required by the Federal law. Agencies try to alleviate the perceived maldistribution of health services and to contain rising costs through CON programs.

Amendments to the 1974 National Health Planning and Resources Development Act established a two-level review process for CON programs. A medical facility must submit a detailed application to the local health planning agency, which subsequently reviews it. State health planning agencies have the authority to grant a CON, but they must carefully consider the recommendation of the local agency.

Minimum criteria and standards for CON review by the States are set forth in the Federal planning law. The State agencies must consider the relationship of the proposed services to the State health plan and to the provider’s long-range plan, the targeted population’s need for the proposed services, alternative means of meeting the need, the availability of resources for the proposed service and alternative health uses of those resources, the relationship of the proposed service to the existing health care delivery system, and special needs of health maintenance organizations (HMOs), among other criteria.

Current Federal law requires hospitals, skilled and intermediate-care nursing facilities, kidney disease treatment centers, rehabilitation hospitals, and freestanding ambulatory surgical centers to submit applications for capital expenditures under State CON programs. States vary in their cover-

age of other facilities, but few cover physicians' offices (see section on "State Certificate-of-Need Laws" below). Some facilities are exempt from the Federal requirement for CON applications for capital equipment, among them Federal hospitals and clinics (e.g., Veterans Administration medical centers). Medical research institutions and HMOs are given special consideration. These entities must notify the State CON agency that they intend to purchase a piece of major medical equipment, for example, and the agency must approve the purchase if specific applicant criteria are met and if need is demonstrated (Public Law 96-79 and Public Law 96-538).

Required applications for CON are triggered under Federal law by types of expenditures and by amounts of such proposed purchases. Proposed expenditures must: 1) exceed the threshold, 2) substantially change the bed capacity of the facility, or 3) substantially change the services of the facility. The original CON thresholds were: 1) \$150,000 for capital expenditures, 2) \$75,000 for annual operating costs resulting from changing services, and 3) \$150,000 for major medical equipment to be used to provide medical and other health services. The CON threshold levels that have been in effect since 1981 are: 1) \$600,000 for capital expenditures, 2) \$250,000 for annual operating costs resulting from changes in health services, and 3) \$400,000 for major medical equipment to be used to provide medical and other health services.<sup>1</sup> For changes in health services, CON applications are required if there is *any* capital expenditure or if annual operating costs exceed the specified operating cost threshold (129). Medical device purchases are included in CON applications in those instances in which the devices are very expensive or in which facility services are changed.

Since 1979, Federal law (Public Law 96-79) has required purchases of major medical equipment that will be used for medical treatment of hospi-

tal inpatients to be covered by State CON laws, regardless of who makes the capital expenditure. Gifts and donations of medical devices that would come under CON laws if they had been bought by the facility are also subject to CON requirements.

Capital equipment initially purchased for research purposes usually must be approved for later clinical use through the CON requirement regarding new institutional services. There are no national data available regarding how much medical equipment has initially been purchased for research purposes and then transferred to clinical service. Thus, the effect of this aspect of the CON regulation on the medical devices industry is unknown.

What are the sanctions or incentives that enforce the Federal planning law's requirement that States have CON laws? First, States that do not have such laws risk losing their Federal planning money. But Federal planning funds have decreased over the past few years, and the program has weakened. Second, and probably more important, if States do not have conforming CON laws, they are supposed to lose Federal funds from several Public Health Service programs (particularly those under the Community Mental Health Centers Act, Comprehensive Alcohol and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, and the Drug Abuse Office and Treatment Act of 1972—see Public Law 96-79, sec. Ids).

The threat of these sanctions persuaded all but one State (Louisiana) to pass CON laws by March 1983 (406), although as of March 1984, only 23 States had CON programs in compliance with the minimum Federal requirements (129). Because the sanctions are not being applied under the present national law, however, Minnesota, Idaho, and New Mexico have allowed their CON laws to expire. For several years, the costs and benefits of the Federal planning program have been questioned by Congress. This debate has resulted in funding the planning program through continuing resolutions that have specified that noncomplying States not be penalized.

The future of the Federal planning program is uncertain. Budget decreases and the expressed intention of the Reagan Administration to dismantle planning have further weakened the existing

<sup>1</sup>States have been given authority to adjust these thresholds to reflect the change in the previous year in the Department of Commerce Composite Construction Cost Index. For States that do so, the thresholds would be \$695,285 and \$289,782. The \$400,000 threshold for major medical equipment may not be adjusted. (See Public Law 97-35 or proposed rule changes in the Jan. 4, 1983, issue of the *Federal Register* (315).)

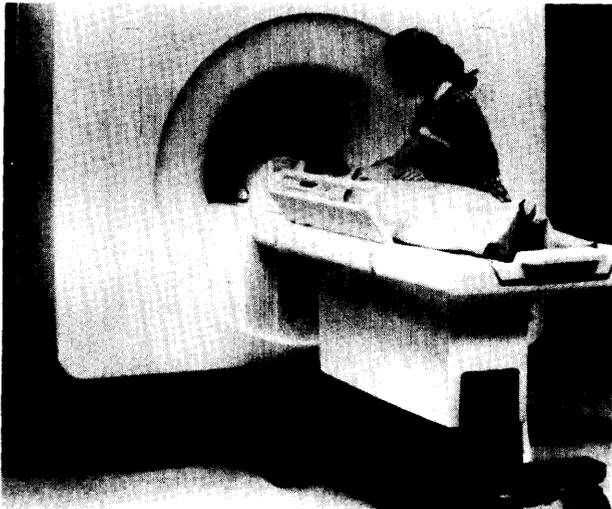


Photo credit: General Electric

Nuclear magnetic resonance (NMR) imaging equipment, shown here, is one of the few medical devices that is expensive enough to be regulated under State certificate-of-need (CON) laws.

program. The Administration, however, seems to be reconsidering its position (453). New CON thresholds have been proposed in Congress (see box N), and the Office of Management and Budget has indicated a willingness to accept thresholds of \$5 million for capital expenditures, \$1 million for changes in institutional health services, and

\$2 million for major medical equipment (453). Although the fiscal year 1985 Federal budget contains no funds for health planning, the Administration has indicated that new, reasonable legislation would be considered favorably (37).

Health planning has many critics, but an in-depth examination of the pros and cons of health planning is beyond the scope of this report. Specific criticisms of the Federal health planning program focus on the difficulty of determining the need for various health facilities and services. Methods of calculating need involve the use of demographic and epidemiologic data and require decisions based on the pros and cons of having excess or insufficient facilities on a periodic or sporadic basis. State and local planning agencies often rely on hospitals and other facilities for their data, which may pose problems of reliability. In considering the need for new medical technologies, data may not be available. State planning agency staffs may not have information on safety, efficacy, and cost effectiveness of new or old medical devices. Furthermore, agency personnel have been criticized for their lack of ability to use the data appropriately (61,111).

The effect of the Federal health planning regulations on medical devices is most distinct in the CON impacts examined in the section on "State Certificate-of-Need Laws" below.

## STATE REGULATION OF PROVIDERS

At the State level, providers of medical devices are regulated in part through State licensure laws for facilities and personnel. They are also regulated through State CON laws, which are required by the Health Planning and Resources Development Act of 1974 (Public Law 93-641) to conform to Federal criteria. Capital expenditure reviews required by section 1122 of the Social Security Act were discussed in the section on "Federal Regulation of Providers" above. Although like CON reviews, section 1122 reviews are State based, the sanctions on facilities for noncompliance with the section 1122 are the withholding of Federal funds under Medicaid, Medicare, and Maternal and

Child Health and Crippled Children's Services programs. The sanctions on facilities for failure to comply with CON, by contrast, are determined by individual States.

### State Licensure of Facilities and Personnel

States have the power and responsibility to determine which providers may treat patients. To ensure a minimum level of quality for providers, State laws require hospitals, nursing homes, and other health care facilities to meet specific standards in order to be licensed to operate. Facility

**Box N.—Legislative Activity in Health Planning, 1983 Congress, 1st Session (1983)**

**H.R. 940 (McDonald).** Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Health Service Act. Introduced Jan. 25, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

**H.R. 1389 (Shelby).** Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Health Service Act. Provides that such repeals shall not affect outstanding loan obligations. Establishes 20-year Federal recovery rights on facilities receiving title XVI construction grants. Introduced Feb. 8, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

**S. 963 (Hatch, by request).** Health Amendments of 1983. Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Service Act. Introduced Mar. 24, 1983. Referred to Senate Committee on Labor and Human Resources.

**H.R. 2935 (Shelby).** Health Planning Block Grant Act of 1983. Replaces title XV (National Health Planning and Development) of the Public Health Service Act with State health planning block grants. Specifies certificate-of-need (CON) program requirements, including thresholds of \$1 million for institutional health services and \$5 million for capital expenditures and major medical equipment. Introduced May 9, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

**H.R. 2934 (Waxman).** Health Planning Amendments of 1983. Amends Public Health Service Act to revise the health planning program under title XV (National Health Planning and Development). Repeals the program effective Oct. 1, 1986. Raises CON thresholds to \$1 million for capital expenditures, \$500,000 for changes in health services, and \$500,000 for major medical equipment. Introduced May 9, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment. Reported to House by House Committee on Energy and Commerce. Placed on Union Calendar for action by full House.

**S. 1778 (Quayle).** Repeals title XV (National Health Planning and Development) of the Public Health Service Act and replaces it with the Health Planning Block Grant Act of 1983. Gives States discretion regarding participation. Repeals this act as of Oct. 1, 1986. Introduced Aug. 4, 1983. Referred to Senate Committee on Labor and Human Resources.

**H.R. 850 (Gephardt).** National Health Care Reform Act of 1983. Among many health care reforms, repeals specified provisions of Public Health Service Act concerning health maintenance organizations, health planning, and health resources development. Introduced Jan. 25, 1983. Referred to House Committee on Energy and Commerce, House Committee on the Judiciary, House Committee on Post Office and Civil Service, and House Committee on Ways and Means. Referred to subcommittees of the listed committees.

standards often include staffing requirements for licensed personnel who have met a set of licensure qualifications, such as education and experience. Virtually all States have hospital licensure laws, but licensure laws with respect to other types of facilities vary. State licensure laws also vary according to types of personnel. The specific standards and qualifications required are decided by the individual States (227).

Some licensure laws are more detailed than others regarding medical devices or, more frequently, necessary staffing and staff qualifications. Licensure laws are similar to the Medicare conditions of participation in their focus on structural aspects of quality assurance, such as compliance with construction codes and public health laws. Licensure regulations tend to be weaker, more ambiguous, and not so well enforced in mat-

ters that are more clearly related to patient care (227).

There has been little research on the influence of State licensure laws on the adoption and use of new medical technologies (227). It is probable, however, that licensure programs have had mixed effects on medical devices, depending on the specificity of the individual laws and how a particular device is related to personnel needs. In clinical laboratories, for example, the strict personnel requirements for laboratory licensure make equipment that reduces the number and skill level of personnel quite attractive (120).

On the other hand, licensure requirements may slow the diffusion of equipment that requires licensed personnel for operation (227). In addition, stringent rules to employ highly trained personnel in laboratories raise barriers to entry of new facilities in the market because of the difficulty of finding and expense of employing the required personnel (120). Both facility and personnel licensure, then, can affect medical device diffusion.

Another characteristic of State licensure programs themselves that probably affects the medical devices industry is the use of professional surveyors to inspect facilities. The subjectivity of some of the judgments needed to decide about licensing a facility can sometimes be the basis for challenging negative outcomes. Also, if review teams have a particular professional orientation, they can encourage the adoption of the best available new equipment (227).

### State Certificate-of-Need Laws

Several States had CON laws prior to the enactment of the National Health Planning and Resources Development Act of 1974. In 1964, New York became the first State to enact and implement a CON law. Twenty-seven States had CON laws by the time the National Health Planning Act was passed. These States were required by 1980 to make their laws conform to the same minimum Federal standards as State CON laws enacted after 1974 (Public Law 96-79).<sup>2</sup> However, State CON

laws differ with respect to the types of facilities covered, the standards and criteria used for CON review, and the amounts of the expenditures for which CON applications must be submitted (406).

As noted in the “Federal Health Planning Regulations” section above, current Federal law requires hospitals and other specified medical facilities to submit applications for capital expenditures under State CON programs. Some States require other types of facilities (e.g., freestanding emergency care centers and home health agencies) to submit applications, as well. Nine States require CON applications for equipment purchases for physicians’ offices (453).

The focus of review when CON laws were first implemented after 1974 was on construction projects (i. e., modernizing old buildings and erecting new ones) and bed capacity changes (61). One of the reasons was that control over the costs of such projects implied control over further duplication of facilities and excess bed capacity that was blamed for some of the increase in health care costs. Another reason for the focus on construction and bed capacity changes when CON laws were implemented was that there were few medical technologies at the time that cost more than \$150,000 (the original CON threshold). Furthermore, hospitals and other purchasers of medical equipment were able to circumvent the requirement for CON applications for equipment purchases in excess of the threshold by dividing orders into smaller expenditures that would not trigger the review process (42). If new laboratories were built or old ones renovated, construction was usually necessary and put the project over the CON threshold. If equipment purchases (regardless of price) changed the health services offered, *or* if the new services (regardless of capital expenditures) resulted in operating costs *over* \$75,000 (again, the original threshold), CON applications would be required (129).

As CON programs matured and as medical equipment changed, more medical devices came under review. Highly innovative machines that altered the practice of medicine, such as the CT scanner, were introduced in the 1970s (see box O). Machines such as CT scanners presented CON agencies with difficulties because of their high cost

<sup>2</sup>Costs and benefits of the Federal health planning program have been debated in Congress for several years. This debate has led to budget cuts and to continuing resolutions that do not enforce penalties on noncomplying States.

**Box C?. -The Impact of Certificate of Need (CON) on Computed Tomography (CT) Scanners and Nuclear Magnetic Resonance (NMR) Imaging Devices**

Many of the issues encountered in today's debate regarding the costs and benefits of NMR imaging devices were also problems encountered when CT scanning equipment was introduced in the 1970s. The CON laws were changed to balance some of the incentives for CT, but their effect on NMR remains speculative.

One of the difficulties in the CON process for CT scanners was the lack of data on safety and efficacy for different medical conditions when CON applications were received (348). Physicians were experimenting with new uses of the machines, and manufacturers were improving the images and reducing the X-ray dosage for their machines. Some hospitals obtained CT scanners for investigational purposes, and when CON applications were later submitted, these institutions already had the machines and experienced personnel on staff. Furthermore, some CT scanners were purchased for hospitals by physicians or groups of physicians, since only hospital purchases were covered by most CON laws. Mobile CT units were also purchased and were able to serve several hospitals (349).

In 1979, CON laws were amended to include major medical equipment purchases for inpatient hospital use regardless of purchaser (Public Law 96-79). This change affected the private purchases of CT scanners for hospitals and the mobile units. Private purchases for nonhospital locations of CT scanning devices were exempt from most States' CON programs. The CON laws may thus have contributed to the maldistribution of CT scanners that was perceived as late as 1980 (23). The maldistribution of scanners has implications for access to care and perhaps for quality of care for the poor segments of the population who most often go to the hospitals that were not able to obtain CT scanners.

The price of head scanners declined over time, and hospitals that had waited to purchase them could do so without submitting CON applications because prices fell below the threshold. A change in the Federal regulations regarding CON programs in 1979 brought the head scanners back into the planning fold by using the "change in service" requirement (349). Upgrading equipment from CT head scanners to body scanners also came under CON review.

NMR imaging devices have been compared to the CT scanning devices because both have been expensive innovations that could change the practice of medicine. Both became popular while still in experimental stages of development. Just as CT head scans were further advanced in development when CT began to affect CON processes, NMR head images are further advanced than NMR body images. CON applications were submitted before there were adequate data from which to evaluate CT scanning equipment (349). Although NMR is still in a research stage, 33 CON applications had already been filed for NMR by October 1983 (451).

The prices of most NMR devices would trigger CON even if the thresholds were raised to the proposed \$1 million for major medical equipment (100). Prices on CT equipment have fluctuated, but whether or not prices will decrease for some or all NMR devices is unknown. NMR devices would also trigger CON for changes in service and if construction costs for building or renovating facilities to house NMR equipment exceed the proposed \$5 million CON threshold. Physical facilities must be modified more for NMR than for CT equipment. Both raise operating costs, and NMR devices require special personnel. When CT scanners first became a CON issue, third-party payment for their use was questionable. That is the case again with NMR. Private investors are purchasing NMR imaging equipment and locating it at nonhospital sites for the use of ambulatory patients. Thus, although NMR device use is still in a research phase, there seems to be a considerable amount of action in the market (100).

and the paucity of data on safety and efficacy. Studies of the effectiveness of CON programs have shown that some States have used them successfully and others have not (133,436). Capital expenditures and health care costs have continued to increase despite CON laws, although both results may vary by State (436). Several researchers have studied the effects of CON on capital expenditures; some have found evidence supporting (which in 1979 was extended to cover any major capital limitation by CON and some have found evidence against it (436). Applications from hospitals and other covered facilities to increase despite CON laws, although both results may vary by State (436). Several researchers have studied the effects of CON on capital expenditures; some have found evidence supporting (which in 1979 was extended to cover any major capital limitation by CON and some have found evidence against it (436). Without regard to the purchaser or to the location of the equipment) (349).

The interaction of CON thresholds and equipment purchase prices is a potential source of influence on the diffusion of new medical devices. Over time, CON thresholds have increased. The prices of medical equipment also change over time as refinements are made or as components instead of a composite machine are sold, for example. The prices of medical equipment may go either up or down.

If new major medical equipment is priced above the CON threshold, delaying its purchase may save a facility money (unless the facility's resulting loss in potential operating revenues is substantial); if the price drops below the CON threshold, the facility may save not only the amount by which the price drops but also the administrative costs of the CON application. In the case of equipment that substantially changes the services provided by the facility, however, CON review would be necessary even if the price were to drop. In addition, facilities are prohibited from dividing projects into parts to avoid CON applications—each project must be a separate project (141).

Under the Federal requirements, State CON programs are to "provide for procedures and penalties to enforce the requirements of the program" (42 U.S. C. 300 m-2). Hospitals and other covered facilities must submit their CON applications to the State or local planning agency and abide by the approvals or denials or suffer the consequences. Sanctions against providers vary among the States but may include any or all of the following: denial or revocation of operating licenses, fines, civil or criminal penalties, and court injunctions (42 CFR 123.408 (b)).

Studies of the effect of CON on cost control have produced no findings to support its ability to control health costs (436). Access to care for some patients has been improved, but there still seem to be excess bed capacity and duplication of services and facilities in some areas and shortages in others, all of which were to have been eliminated through CON (61).

There have been many studies of the impact of CON programs on capital expenditures (436). One of the early studies by Salkever and Bice showed that in States with CON laws, the number of beds decreased, but total hospital investment and assets per bed (which relate to medical devices) increased from 1968 to 1972 (270).

Hellinger, testing the hypothesis that the amount of hospital investment in States with CON laws would be less than it would have been without the CON programs (148), concluded that CON legislation had not significantly decreased capital expenditures. He then speculated that there would be a lagged effect because hospitals had anticipated the passage of the CON laws and spent higher than usual sums in the period before their implementation.

Warner has pointed out that because they do not specifically consider operating costs associated with capital purchases, CON programs do not evaluate whether equipment will ultimately save costs or increase costs (450). Operating costs of capital expenditures continue to be a source of health care cost increases (64).

Yet another study showed that in States with hospital rate-setting programs, increased capital expenditures may not lead to higher operating costs (96). Specific devices may be affected dif-

ferently in different States. Russell found that the diffusion of cobalt therapy was not discouraged by the CON law in New York, but CON laws in other States have discouraged the technology's adoption of cobalt therapy (266).

A July 1982 study by the Wisconsin Hospital Association used data from the Wisconsin Hospital Association CON Data Base, its 1982 CON Survey, and State and local CON agencies' grant applications for 1978-81 to analyze the cost effectiveness of Wisconsin's CON program (462). The association found, using particular assumptions, that CON costs far outweighed the benefits. The investigators concluded that Wisconsin's CON program was not cost effective, did not suppress applications for capital expenditures (i.e., did not have a sentinel effect), had had its decisions reversed through administrative appeals, and had been unfocused and inconsistent in the substance of its reviews and in its determinations.

Looking at application and approval and denial data gives the impression that CON programs are accomplishing some of their goals. From 1979 to 1981, States reviewed more than 20,000 CON applications, which totaled more than \$31 billion. Almost 10 percent of the applications were denied, saving an estimated 15 percent of the proposed expenditures (406).

These aggregate figures hide the facts that CON may have deterred an unknown number of applications and purchases and that the quality of the rejected applications is unknown. Some consultants specialize in CON applications (148), and manufacturers may send staff to assist hospitals in their CON applications (208). Small hospitals with less sophisticated technology are probably at a disadvantage in attracting or being able to pay for such help, and this may exacerbate the maldistribution of high-technology devices. Also among the unknowns are whether the distribution of services is being made equitably among the population and whether approved projects were needed more than those denied.

The costs of the CON programs themselves are substantial. In 1982, total Federal and State costs of administering CON programs were \$16.9 million (406). Additional costs were probably offset by the CON application fees charged by half the

States. Application fees and the other costs borne by the applicant facilities may discourage some applications. Whether the applications discouraged are frivolous or important for the health of the affected population is unknown. It is likely that examples could be found at either extreme.

Weighing the costs of the CON programs against their benefits is difficult because of the existence and interactions of Federal, State, and local regulatory programs and of complex goals. Competing goals, such as the elimination of excess beds and the assurance of access to health care, not only present CON programs with problems while they are evaluating applications, but also exacerbate the problem of identifying and measuring the benefits of regulation and planning.

CON programs would lose some of their control over capital expenditures if the thresholds were raised to the levels proposed by the Office of Management and Budget (i.e., \$5 million for capital expenditures, \$1 million for changes in services, and \$2 million for major medical equipment). Clearly, fewer projects would require CON applications. Even some new facilities would be below the threshold unless they were specifically covered by CON laws. New freestanding emergency care centers, for example, have averaged \$634,000 in building, land, and capital equipment costs (292). Capital expenditures that change institutional services and increase operating costs by \$1 million annually would still require a CON, but their numbers would probably be small. High thresholds and the resultant low number of CON applications would save administrative costs for Federal and State governments and for the facilities,

If the Federal health planning program expires, the State CON laws will be voluntary (as far as the States are concerned). In 1984, the Office of Health Planning of DHHS has estimated that 37 of the States that have CON laws would keep them without the Federal requirement (129). A dozen States have "sunset" clauses that allow the CON laws to expire on specific dates; some others have sunset provisions tied to the anticipated demise of the Federal health planning program. Again, some States have CON laws that are more stringent and some have more lenient regulations than the Federal CON requirements.

The financial incentives for hospitals under Medicare's DRG hospital payment system currently being implemented (see ch. 3) change the roles of the CON laws and the planning program in general. Some of the effects will depend on how capital costs will be handled under the DRG system.<sup>3</sup> With DRG payment for inpatient operat-

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<sup>3</sup>Capital costs are now paid on a cost-reimbursement basis but will probably be paid on a different basis by 1986, since Congress mandated studies of how to treat capital costs under the DRG hospital payment system (Public Law 98-21). Any new capital payment method can be expected to change the hospitals' incentives regarding capital expenditures.

ing costs (capital, outpatient, and direct teaching expenses remain "passthroughs"), hospitals have financial incentives to purchase technologies that lower their operating costs per case; and if they are expensive, these technologies may come under CON scrutiny. An anticipated response to the DRG hospital payment system is the movement of technologies from tertiary to primary care sites. This movement may be retarded in States where facilities other than hospitals are included under CON. The effect of such movement on costs will depend on whether the primary sites were replacing or supplementing hospital care and on the extent of total use that results.

## DISCUSSION AND POLICY OPTIONS

Regulation of the providers of medical devices has been undertaken to control medical care costs, increase access to medical care (including devices), and control quality of care. Available evidence on the success that Federal and State regulation of providers has had in meeting these objectives is inconclusive. Health care costs continue to rise at a higher rate than the overall Consumer Price Index. Access to care is still a problem for some poor patients or patients in particular locations. Quality of care is difficult to define and measure, and problems remain in assessing quality concerns.

Conditions of participation for providers of services to Medicare beneficiaries and the new Federal requirement that hospitals contract with PROS (utilization and quality control peer review organizations) in order to be paid by Medicare have quality as well as cost implications. Changes in conditions of participation proposed by DHHS in January 1983 would give hospitals more flexibility in the provision of inpatient care, and medical devices may be affected even less under the new conditions than they were under the original set of conditions. Efforts have been made in the PRO regulations issued by DHHS to address previous problems with the PSRO program concerning quality review by requiring that evaluations of PROS have both cost and quality components. Evaluations of PSRO programs focused on cost-containment goals without adequately measuring

quality of care. Thus, for example, such evaluations emphasized the ability of PSRO utilization reviews to decrease length of stay and hospital admissions.

Section 1122 of the Social Security Act pertains to review of capital expenditures and the Medicare, Medicaid, and Maternal and Child Health programs. Few medical devices come under section 1122 review because of the high threshold (\$600,000). However, those devices that do also trigger CON review. The penalty for facilities that disregard section 1122 reviews would be stronger if the Social Security Act required the withholding of Federal program payments for operating costs associated with unapproved capital investments.

The Federal Health Planning and Resources Development Act requirement that States impose CON regulations on hospitals and other facilities in theory should have formed the strongest regulatory mechanism concerning the adoption and use of medical devices. Although CON regulations have attempted to contain costs and improve access, the evidence of their effect on medical devices is inconclusive: it is unclear whether CON laws have influenced the adoption and use of medical devices.

The results obtained by State CON laws may reflect certain characteristics of these laws. First, the laws have high thresholds for capital expend-

itures resulting in the coverage of few devices under these laws, and the laws ignore future operating costs. Second, the focus on hospitals by almost all the CON laws—although other sites are covered by some States (including physician offices in nine States)—may have contributed to duplication of technologies within the system. Third, the lack of a limit on the amount a CON agency can approve lessens the potential impact of CON on total costs. Fourth, the CON process is a reactive process in the sense of being dependent on the submission of CON applications by medical facilities. And fifth, political interactions among consumer patients, providers, and CON agencies influence the decisionmaking process.

One problem with concluding from the mixed evidence that CON regulations have been ineffective is that incentives for health care facilities to buy whatever they wanted were embedded in cost-based reimbursement by third-party payers, and not all purchases were subject to CON requirements. Duplication of equipment among hospitals and other facilities in the same geographic area continues at least in part because facilities want to attract patients and physicians by providing up-to-date equipment. CON programs do not have the power to decide how much equipment is used or the ways in which it is used. Utilization and quality review programs can encourage the appropriate use of technologies, but decisions about use are basically left to physicians (and in some cases patients).

CON agencies have been hampered by unavailability of data on the health of the population and on the safety and efficacy of some new medical equipment, undeveloped techniques for determining need, insufficient budgets to hire appropriate planning agency staffs, and the political sensitivity of rationing health care. Furthermore, the regulatory agencies responsible for CON were advised by committees representing not only consumers but also the health care providers. CON decisions were thus compromises among parties with conflicting interests. All these difficulties have been exacerbated by constantly changing technology.

The following options present a range of possibilities regarding CON programs, from changing current regulations to eliminating them. The

options concentrate on CON because of the relative availability of information on these programs and because of the direct impact on the medical devices industry.

*Option 1: Expand the National Health Planning and Resources Development Act to require State CON laws to cover purchases of medical equipment regardless of setting.*

This option would attempt to make the incentives of the Federal health planning act more neutral with respect to the location of certain medical devices by requiring that in addition to the hospitals, dialysis centers, and other facilities now covered by the act, physicians' offices, diagnostic centers, and other facilities now excluded by the legislation be required to submit CON applications before purchasing expensive medical equipment. Control over all sites of care would remove current incentives to place expensive devices in certain, mainly nonhospital, settings without regard to cost effectiveness. Maldistribution of medical equipment might still occur, though, because of the reactive nature of the CON process and the influence of other factors on placement.

Several States already have CON programs that cover major medical equipment purchases regardless of setting or ownership. Some States are encouraging hospitals to share equipment, such as new NMR devices in Nebraska (291). More sharing would be anticipated if all settings were covered, especially if a State had a limit on total CON approval. If such sharing became commonplace, different arrangements might be necessary to ensure quality (349). For example, facilities now carry liability insurance for their own physicians to use their medical devices; this type of insurance might have to be extended to other physicians using the devices.

Greater administrative costs to governments and providers from increasing the number of applications would result under this option. Although few medical devices are covered by CON thresholds, applications would increase since many of the settings that would be added by this option already purchase high-cost medical devices for which hospitals and other facilities are cur-

rently regulated. Regulatory staff would have to learn about health care delivery and needs for devices in these currently uncovered settings.

*Option 2: Amend the National Health Planning and Resources Development Act to limit the level of capital expenditures that State CON agencies may approve in a year.*

Because the funds for health care facilities and medical devices are limited, not all projects can or should be funded. Current CON approval or denial decisions are not necessarily made in light of information on different types of projects, and tradeoffs are not necessarily considered. A limit on the level of capital expenditures would necessitate comparisons among projects.

The Federal requirement that CON applications be batched so that similar projects are evaluated at the same time does not address the issue of tradeoffs among dissimilar projects. Hospitals that want to purchase new CT scanners, for example, may have to wait several months until the batch of applications is evaluated. Those applications are reviewed without regard to applications for other types of equipment or for buildings.

The Commission on Capital Policy of the American Health Planning Association recently recommended that future cost-based reimbursement for capital be limited by each State, subject to a Federal standard (5). The commission urged the adoption of limits that reflect the relative need of each State for modernization of facilities and for new services and facilities. It further suggested that capital payments within those limits be allocated by means of a planning and capital expenditure review process, presumably similar to the existing system.

If Medicare's DRG prospective payment system for hospital operating costs were extended to other payers, a State limit on total CON approval would become less useful. The reason is that hospital acquisitions would be constrained by the financial pressures to limit operating costs. A limit on the level of expenditures a CON agency could approve would also be less necessary if capital expenditures were included in DRG payments.

A major obstacle to the implementation of this option is the limit itself. Congress or the Admin-

istration might be the decisionmaking body for choosing the limit, but *how* would the limit be chosen? Techniques for determining a community's need for specific medical devices are still controversial. Determination of the need for the total capital expenditure in health care is clearly problematical. How much is the Nation or each State willing to pay overall for health care? How could that amount be apportioned between capital and operating costs, excluding preventive care for the moment? Would the limit be applied nationally or at the State level or locally? How should the budgeted limit be apportioned among the geographic regions or among the health care delivery sites?

The ultimate problem would be the selection of individual projects for funding in light of the lack of a generally valid decisionmaking method and the lack of theoretical or empirical predictions that the results of such a limit would be efficient or equitable.

*Option 3: Amend the National Health Planning and Resources Development Act to eliminate the Federal CON requirement.*

State CON programs have not been uniformly successful in controlling the costs and quality of, or improving access to, health care delivery. Health care costs are rising at a great rate, and some rural areas and urban public hospitals do not have the minimal requirements for some services that are outlined in the "National Guidelines for Health Planning" under the Federal health planning program. This option would eliminate the Federal requirement that States have CON laws, but would permit those States that wanted to continue their programs to do so.

Implementation of this option would eliminate the State and Federal Governments' administrative costs for the Federal program. It would also relieve hospitals—and in some States, other facilities—of the costs of application fees, personnel, and delays involved in the CON process.

The method of treatment of capital expenditures by the Medicare payment system will affect the need for regulations, especially if the DRG-based prospective payment system expands to other payers. In the past, Medicare has reimbursed hos-

pitals for capital equipment on the basis of costs (see ch. 3). Medicare's DRG prospective payment system provides incentives for hospitals to reduce operating costs. If cost reimbursement for capital continues under Medicare's DRG payment system, hospitals will face incentives to purchase medical devices that will reduce operating costs. If payment for capital costs is more restricted, the incentive to purchase such devices will be weakened (but not eliminated).

No matter how capital costs are treated, socially desirable medical devices that raise operating costs may not be financially desirable to hospitals. CON programs could play a role in the proper diffusion of socially desirable but very expensive technologies if they could encourage particular facilities to purchase such technologies by offering special treatment on other applications, for example. At present, this kind of negotiating role would require changes in some CON laws.

Medicare's DRG-based prospective payment system itself may change the need for CON programs or for the national planning effort, especially regarding distribution of services. If the incentives of DRG payment work as anticipated, hospitals will specialize in treating patients in those DRGs in which they are efficient. Such specialization will follow a hospital's efforts to work with its medical staff to be cost conscious and to reduce the use of very expensive services. Some hospitals will continue to try to attract physicians and patients through purchases of the latest medical devices, but others will cut back some services.

Specialization among hospitals is likely to result from the dropping of services that do not pay for themselves through DRG payments. For example, a hospital that finds that its costs for staff, facilities, and equipment for coronary care are lower than the relevant DRG payment rates may specialize in coronary care. The same hospital may drop its pediatrics services if its costs are higher than the relevant DRG rates. Specialization could decrease duplication of medical devices and possibly eliminate excess capacity and lower excess use. CON programs may become unnecessary in light of these strong cost-containment incentives for hospitals, although the problem of duplication of services among nonhospital settings not covered by CON could be worsened.

If specialization decisions were made on a purely cost basis, however, it is clear that not all services or medical devices would be available to all segments of the population: areas of low population density or low income would suffer. The current planning process has not solved the problem of inequitable distribution of facilities and services. Some communities and population groups are still underserved, while certain areas have too many hospital beds. In addition, health planning has not thus far ameliorated the problem of public hospitals, which treat a disproportionate number of poor and elderly patients and which do not have the funds to renovate or to purchase necessary equipment.