Appendixes

Appendix A.— Policy Alternatives

(Reprinted From *Policy Implications of the Computed Tomography (CT) Scanner,* Office of Technology Assessment, August 1978)

The computed tomography (CT) scanner is a new diagnostic device that represents an important advance in medical detection. Studies show that CT scanners perform reliably and provide accurate diagnoses of abnormalities in the head and abdomen. As a relatively safe and painless procedure, CT scanning can replace several less safe and more painful technologies, such as pneumoencephalography. CT scanning has been readily accepted by the medical profession, and its use is expanding rapidly. To the extent that a fundamental problem with CT scanning exists, it lies not in the existence of the technology, but in its appropriate use.

Although this study focuses on CT scanners, its findings are applicable to the general problem of appropriate use of diagnostic medical technologies. Appropriate use includes considerations of safety, efficacy, and cost. Overuse of a technology may lead to both excessive expenditures and unwarranted risk to patients; underuse may result in delayed detection or prolongation of medical problems. In either case, the study demonstrates basic policy problems related to the appropriate use of medical technologies.

Use of a diagnostic medical technology such as a CT scanner depends on many factors: Some increase and others restrict use. A principal and obvious factor is the desire of physicians to provide good care for their patients. Attempts to identify medical problems and to refine diagnoses lead physicians to use the technologies available to them. Medical education also predisposes physicians to liberal use of diagnostic technologies by emphasizing thoroughness rather than discrimination and concern for costs. The current medical malpractice situation further encourages the use of diagnostic tests to avoid error. In some instances, patients themselves request that physicians perform diagnostic tests. Although these are important issues, this report has not addressed medical education, malpractice, and patient demand. Rather it concentrated on available information, governmental regulation, and financing.

After their formal training, physicians continue to receive information about medical technologies from scientific meetings, professional publications, colleagues, manufacturers' representatives, and their own clinical experience. Two Federal agencies, the Food and Drug Administration (FDA) and the National Institutes of HeaIth (NIH), develop and disseminate such information. By law, manufacturers of drugs and medical devices must submit to FDA data that supports claims made in *labeling. NIH* conducts evaluations of certain medical technologies and makes the results available to the public. However, as illustrated by this study, no single Federal or private policy establishes a formal, systematic process to develop needed information about medical technologies. Nor is there a clearly defined mechanism for disseminating what is known to all appropriate parties.

Without such information, physicians appear to test new technologies using a variety of methods to develop a sense of their worth empirically. Unfortunately, these methods are often not designed to yield statistically reliable information. This informal experimentation *can* both retard the early application of valuable technologies and advance the use of questionable ones. Without valid information obtained from well-designed studies, physicians face a very difficult task in deciding on the appropriate use of new technologies.

Prevailing methods of financing medical care provide incentives for additional use of technologies, regardless of their marginal value. Health insurance programs have continued previously existing fee-for-service payment of physicians; performance of additional tests thereby generates additional revenue for the physicians. Hospitals are reimbursed on the basis of their costs or charges. These methods at the least facilitate and at the most stimulate providers to prescribe additional use. Under such a system, providers have little incentive to weigh the benefits and costs of additional tests.

The regulatory framework created by FDA, the Professional Standards Review Organizations (PSROs), and capital expenditure laws also affects the use of medical technologies, in a restrictive sense. FDA requires proof of safety and effectiveness before drugs and devices may be marketed. The PSRO program was designed to establish norms and standards for hospital utilization and medical care provided under medicare and medicaid. And review of proposed capital expenditures is aimed at avoidin$_g$ unnecessary duplication of facilities and promoting their efficient use. Unlike many of the other factors affecting technologies, these programs may restrict their use. The PSRO program and capital expenditure review were created in part to counter incentives for greater use, especially from financing methods.

The following sections present alternatives that might improve the use of medical technologies such as CT scanners. The alternatives are presented in three sections, each addressing a specific category of governmental policy: Section 1 focuses on developing and disseminating information on efficacy and safety; section 2 on regulatory policies; and section 3 on financing. The alternatives in each of these sections illustrate, but do not exhaust, possible options. Nor are they necessarily mutually exclusive. Each alternative should be measured against the continuance of current policies and their consequences as well as against the consequences of the alternative itself. These alternatives represent broad guidelines for policy. As such, they do not consider in depth the more technical aspects of implementation, such as the mechanisms for evaluating efficacy, specific criteria for utilization review, methods of cost accounting, or details of ratesetting.

1. Information on Efficacy and Safety

Many decisions concerning the use of a medical technology depend—directly or indirectly—on an assessment of its efficacy and safety. Much of the available information on efficacy and safety is not derived from well-designed controlled clinical trials, epidemiological studies, or analyses of clinical experience. Instead, informal judgments evolve, judgments based primarily on the experience and perceptions of individual physicians. Judgments of this type, when they do not accurately reflect the efficacy and safety of a technology, may contribute substantially to inappropriate use.

The development of information on efficacy and safety involves identifying the technologies to be studied, conducting the appropriate evaluations, and synthesizing the results of those evaluations and relevant clinical experience. The synthesized information may then be disseminated to the individuals and organizations most in need of guidance. Although simple to delineate on paper, this process of synthesis and dissemination can be complex and difficult to implement.

This section presents two policy options designed to address the needs of medical care decisionmakers for efficacy and safety information. The first concerns the development and dissemination of the information. The second requires the type of synthesis that analyzes information to produce formal policy judgments about a technology's efficacy and safety. This section and the alternatives presented in it are concerned only with developing and disseminating information.

Together, the two alternatives, if adopted, would increase the amount of information available to physicians in their use of medical technologies The information would also be helpful to planners, regulators, and public policy decisionmakers. As explained in alternative 3 of the following section, FDA already requires the development of information and makes certain policy judgments about the safety and efficacy of medical technologies. The alternatives in this section would substantially enlarge these existing processes,

As discussed in chapter 3, information about efficacy is used or could be used by many Federal programs, as well as by providers of medical care. Decisions and policies based on efficacy may now be inconsistent as each user defines efficacy in its own way. As described in chapter **3,** only FDA has a formal definition of efficacy at present, and that definition merely ensures that the evidence substantiates the claims of the manufacturers. But FDA's decisions on efficacy and safety are of limited value to health planning agencies, PSROs, and reimbursement programs.

A general definition of efficacy could be developed for all types of medical technologies—preventive, therapeutic, and diagnostic. No medical technology is beneficial in all circumstances, and some technologies can be extremely beneficial only if used in very limited situations. Therefore, the efficacy of a particular technology must be related to a defined population, a given medical problem, and particular conditions of use. A complete specification of efficacy encompasses all three of these factors. '

> Alternative 1: Establish a formal process to identify medical technologies that should be assessed for efficacy and safety; conduct the necessary evaluations; synthesize the results from the evaluations and from relevant clinical experience; and disseminate the resulting information to appropriate parties.

Except for new drugs and, potentially, new medical devices, the Federal Government's identification of technologies warranting study occurs in an ad hoc manner. Often, decisions to evaluate a technology depend on the curiosity of investigators or Federal program administrators. Few efforts have been made to coordinate the selection of technologies to be studied with the informational needs of relevant governmental agencies and private groups.

[1]Efficacy is defined as the potential ber efit to Individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. These idealconditions may be approa(hed in research settings, but are unlikely m average practice. Efficacy, then, represents an outer limitto benefit.

No existing Federal procedure systematically identifies those technologies that are most in need of investigation. Indeed, no formal set of criteria has been developed for establishing such priorities. The private sector identifies medical technologies to be assessed for efficacy and safety through an even more informal process. As described in chapter **6, how**ever, some efforts have been initiated by organizations such as the Federal Health Care Financing Administration and private Blue Cross-Blue Shield *to* identify and develop information on possibly inefficacious or unsafe technologies.

Various Federal agencies currently have responsibility for conducting or funding studies on efficacy and safety, although in each case their mandate is limited and often ambiguous. The NIH effort is by far the largest; that agency spent approximately $100 million on more than **750** studies during fiscal year 1975. The emphasis at NIH is on new technologies, rather than on those already diffused; [2]thus, existing technologies receive relatively little scrutiny. Similarly, drugs and biologics receive more attention than devices or medical and surgical procedures.

No Federal policy focuses responsibility for the dissemination of efficacy and safety information. Although NIH and FDA both disseminate substantial amounts of information, their efforts are hampered by various factors. For example, NIH historically lacks working relationships with many of the parties in need of the information. Although FDA obtains information on efficacy of drugs and devices from manufacturers, most of that information is considered to be proprietary and *is* not released in that form by FDA to the public or to providers. In addition, the information disseminated is often not in a form readily usable by parties in need.

This study of the CT scanner illustrates some of the consequences of using the present informal assessment process, Although the CT scanner has been the subject of much publicity since its introduction, few well-designed evaluations of its efficacy and safety have been conducted, Despite this dearth of information, CT scanning has been more fully evaluated than many other diagnostic technologies.

Instead of continuing the present informal assessment system, the process could be made explicit and formal as indicated by this alternative. The process could be applied to both existing and new medical technologies. With the implementation of an explicit, formal system, criteria could be developed for screening the thousands of existing and future medical technologies to establish priorities for investigation. These criteria could take into account factors now excluded or only minimally included in the process of assigning research priorities. Such factors as needs of health planning agencies and third-party payers and the level of expenditures for the technology could be included in the criteria to be established.

Also, under this alternative, an agency or agencies would be given explicit responsibility for conducting studies of efficacy and safety or ensuring that they are conducted, for synthesizing information to appropriate parties, (Two bills before Congress, H.R. 12584 and S. **2466,** would create an office within the Department of Health, Education, and Welfare (DHEW) to evaluate medical technologies,) The direct anticipated result of this alternative is the production of science-based information for use by medical professionals, policy makers, Government agencies, and the public.

This alternative is not designed to change the current processes of introducing and using medical technologies except to increase the amount of validated information available. The present process allows a broad and varied experimentation process to occur with new medical technologies. Through its processes of careful human experimentation, the present system also permits technologies to be used early in their development. Controlled clinical trials, epidemiological studies, and other forms of technology evaluation are often lengthy activities. Thus, the development of information on efficacy and safety can be a time-consuming process. Under this alternative, diffusion and use of a medical technology would not necessarily be postponed until the conclusion of the evaluation process.

Implementation of this alternative could be costly. Controlled clinical trials are expensive: An average trial funded by NIH costs more than $100,000 per year, and those for surgical procedures or expensive technologies may be several times higher. Formalizing activities under this alternative is likely to increase substantially the number of trials because the screening and synthesizing processes would identify problems with technologies and gaps in efficacy and safety information. A large number of medical technologies might warrant careful examination, requiring complete reviews of available information and attention to clinical experience. The process outlined would make cooperative trials (such as many of those of the National Cancer Institute) more feasible, a development that could reduce the magnitude of the increase in the trials.

A distinction can be made between changing the total use of medical technologies and reducing inappropriate use (e.g., of technologies that are under-

[2]Diffusion of a technology refers to the process of adoption from development until general acceptance

used or overused). This alternative makes the latter possible, though it does not ensure it. Reduction in the use of certain technologies, following evaluation, might be offset by increased use of other technologies, some of which may themselves be unevaluated. The relative magnitude of these three factors—reducing use of overutilized technologies, increasing use of underutilized ones, and the unpredictable shifting of utilization patterns from one technology to another—will in part determine the effect of this alternative on total use of medical technologies and on expenditures for medical care.

Alternative 2: As part of alternative 1, establish a formal process for making official judgments about the efficacy and safety of medical technologies.

Under current law, FDA must determine the efficacy and safety of a drug or device before it can be marketed. No Federal organization is responsible for officially determining the efficacy and safety of medical and surgical procedures. At least two components of the Public Health Service (NIH and the Office of Health Practice Assessment) are attempting to develop formal systems to synthesize information and arrive at decisions on particular medical technologies.

The synthesis process of alternative 1 could take many forms. It could collect and analyze existing information, or it could attempt to identify gaps in existing knowledge as a guide for further research. Under this second alternative, synthesis would involve collecting and analyzing available information in order to produce official policy judgments about the efficacy and safety of the technologies under examination.

This alternative would establish a process whereby relevant information on a medical technology is critically evaluated. The evaluation would result in a judgment, or policy decision, as to a technology's efficacy and safety. This alternative would be integrated with alternative 1. The judgments could contain detailed information on a wide range of indications for appropriate use of the technology. Thus, they could be broader than FDA's current determinations for marketing approval,

Providing official judgments to relevant individuals and organizations would add to the information available to them for making decisions. However, those individuals and groups would still make the final decisions. The judgments about efficacy and safety might be issued as guidelines or as recommendations. They would not be binding. This second alternative would only produce information; it would not be a regulatory process.

Such official information might reduce the errors in judgment that such individuals and organizations make. However, mistakes made by the group developing the judgments, while perhaps fewer in number, would have broader ramifications because of their official nature. Since mistakes are inevitable and judgments of efficacy and safety can change as additional information becomes available, this alternative would require a substantial degree of flexibility in operation. The process outlined in this alternative and alternative 1 could be used initially for a small number of technologies to test its feasibility. An evaluation of CT body scanning, for example, could produce judgments about the types of benefits likely to result for certain kinds of patients and specific medical conditions.

This second alternative would almost certainly have an effect on the current medical malpractice situation. The existence of official, though voluntary, statements as to the efficacy and safety of a technology might become the standard for judging whether a provider properly used that technology.

The major controversy surrounding this alternative would be determining the process that would be used to make such scientific judgments. Because such judgments could be used to decide whether a technology is to be reimbursed and where it can be useful, this alternative could become the focus of considerable political and economic pressure. Care would have to be taken to see that the process is both timely and scientifically appropriate.

2. Governmental Regulatory Policies

In an attempt to offset powerful incentives encouraging the use of medical technologies, Congress has established three regulatory programs: the FDA, the PSRO program, and capital expenditures review. FDA regulates the marketing of drugs and devices. Marketing requires prior FDA approval that the technology is safe and effective, and advertising is limited to the approved conditions. FDA does not have authority to restrict subsequent use by physicians or patients. PSROs evaluate appropriateness of care given to medicare and medicaid patients. PSROs may establish standards for the use of specific medical technologies, such as CT scanners, although few such standards have yet been developed.

State certificate-of-need laws require prior approval for capital expenditures greater than a certain amount, usually $100,000 to $150,000. Federal and most State laws cover hospitals, but exclude private physicians' offices. In general, capital expenditure laws do not regulate use of facilities or equipment

once they are in place. The Social Security Act also restricts payment under medicare to services that are reasonable and necessary for diagnosis, treatment, or improved functioning.

Inadequate information about efficacy and safety handicaps the effectiveness of these three programs. FDA obtains information about efficacy and safety from manufacturers, but that information is limited to certain uses of the drug or device. PSROs, reimbursement agencies, and State and local planning agencies need information about the appropriate use of a technology—the population benefiting, the medical problems affected, and the conditions of use under which the technology is safe and effective. Further information is required concerning the substitution of a new technology for existing ones. Both the PSRO and the health planning programs are new and not yet fully implemented. In addition, lack of universal coverage facilitates circumvention of these programs.

This section includes alternatives concerning the use of medical technologies, capital expenditure review, and medicare reimbursement. Alternatives 1 and 2 from section 1 would facilitate alternative 3 and would be necessary for alternative 4. Alternative 3 would restrict the use of medical technologies to those indications approved by FDA for marketing purposes. Alternative 4 would link medicare reimbursement to the information and judgments of alternatives 1 and 2. And alternative 5 would expand the regulation of capital expenditures to include all purchases of medical equipment regardless of setting or ownership.

Alternative 3: Authorize a Federal regulatory agency, such as FDA, to restrict the use of medical technologies to the conditions of use specified in the FDA-approved labeling.

When FDA approves a drug or device for marketing, it also approves the specific wording of the product's labeling, i.e., the written information used by the manufacturer to describe the product. Labeling (which includes package inserts) lists medical conditions (and possibly populations) for which the drug or device is deemed to be safe and effective and warns about possible side effects.

These "indications for use" are usually not exhaustive. A manufacturer that has conducted premarketing clinical tests to evaluate safety and effectiveness for defined medical conditions and population groups could then seek marketing approval only for those conditions. Thus, the FDA marketing approval process might consider only a portion of the possible indications or contraindications for a new drug or device.

Use of drugs and devices by physicians and patients, however, is not restricted to the approved conditions. Although the manufacturer provides only the approved information to physicians and other providers, this information is in effect merely advice. Nothing in the law prevents the use of drugs or devices for conditions other than those specified. (A bill before Congress, S. 2755, would restrict distribution of drugs to particular providers.)

Uses of a technology for conditions other than those approved by FDA are not necessarily inefficacious. Conceivably, some potentially efficacious uses are not evaluated prior to initial marketing approval by FDA. However, the absence of a particular use from the list of approved uses implies that sufficient information is not available to determine the technology's efficacy for that use.

Examples can be cited of beneficial uses that were neither anticipated nor evaluated by the manufacturer but were later adopted by practitioners. Use of the drug propranolol for treating hypertension (high blood pressure) is such an example. Other unevaluated uses, however, have been shown to be medically unjustified when investigated after the drug or device was marketed. For example, chloramphenicol has often been used for upper respiratory infections when equally effective and less toxic drugs were available. The balance between positive and negative effects of unapproved uses of drugs and devices is difficult to determine. One factor is clear—unapproved uses usually have not been verified by the rigorous clinical research that is necessary to gain FDA approval.

Allowing physicians to use technologies for unapproved uses has resulted in a de facto research or experimentation process. Formal clinical investigations of a new use must proceed under an FDA-monitored Investigational New Drug (IND) process for drugs and under a similar process for devices. Unapproved use by physicians and patients could be considered an unofficial clinical investigation. This result can be either beneficial if a new efficacious use is found or harmful if the use is unsafe or ineffective. Also, aside from the technical questions of efficacy and safety, moral or human rights questions may be raised by this unapproved application.

This third alternative would make FDA decisions binding on physicians. Drugs and devices could be used legally only in accordance with the indications for use specified by FDA's marketing approval. Other uses would be allowed only as part of an approved IND or an investigational process for devices. The investigational process for unapproved uses, the mechanics of which could be similar to the current

process, could replace the present practice of unapproved use. A scientific process evaluted by FDA or another agency charged with the task could add validated indications or contraindications to the approved labeling for a drug or device. This alternative is based on marketing approval, which is now limited to drugs and devices; it would not cover medical and surgical procedures.

The indications for use comprise one aspect of efficacy and safety, as noted above. Therefore, this third alternative would be most effective if generally accepted and comprehensive definitions of efficacy and safety were developed. In addition, a publication listing the FDA-approved indications for use of all covered technologies might be necessary to inform physicians who rely on these technologies.

The principal intention of this alternative is to improve the quality of medical care by ensuring more appropriate use of medical technologies. Fewer patients would then be subjected to unapproved and unscientific uses of technologies. Instead, medical technologies would be more likely to be used in accordance with valid scientific information.

A probable consequence of implementing this alternative would be an increase in premarketing clinical investigation to determine appropriate indications for use, The number of such investigations would depend on the proportion of potential uses that had already been investigated.

This alternative could affect the timing of using a technology for a new indication. Use of the technology for the new indication would not be permitted until the experimentation process had been completed (although some use would obviously occur as part of the experimentation process itself). However, once a use had been demonstrated to be efficacious and safe, the manufacturer would be allowed to advertise that use. This advertising promotion might result in diffusion of the new use to a larger number of individuals in a shorter period of time than occurs under the present system. However, if no firm or other organization decided to conduct investigations and seek approval for a particular condition of use, that potential use might go undetected.

The financial costs of this third alternative are not predictable. Additional clinical trials would increase the costs of bringing a technology to market. The net cost to manufacturers is not clear. They would bear the costs of extra clinical trials, but might receive revenue from addition sales if a new use gained approval. A system of financing additional evaluations of efficacy and safety could be developed, possibly through a combination of manufacturers, patients, and third-party payers. Expenditures for the use of many technologies might fall if third-party payers and patients did not have to pay for unapproved uses, But expenditures on new uses might rise.

Adoption of this alternative would require a system for ensuring compliance. One can imagine very elaborate enforcement measures requiring additional paperwork and specialized personnel that are not readily available. A more simple approach would rely on the good faith of providers. A provider found to be noncompliant would be penalized, but compliance would otherwise be assumed.

The practicality of this third alternative is questionable. Although laws and regulations can mandate this alternative, their enforcement could be cumbersome and expensive. Monitoring, let alone altering, physicians' use of medical devices and drugs is difficult. In addition, the cost of enforcement might exceed the benefits. At a minimum, however, enactment of this alternative might increase providers' awareness of their legal liability in using technologies for unapproved uses and might lead them to operate within the approved investigational process. In fact, approved uses might serve as a basis for liability.

Alternative 4: Link medicare reimbursement to the information and judgments about a technology's efficacy and safety that would result from alternatives 1 and 2.

Medicare administrators have interpreted the provision of the Social Security Act limiting payment to reasonable and necessary services as allowing medicare to withhold payment for experimental procedures whose efficacy has not been determined. It was under this provision that medicare withheld payment first for CT head scanning and then for CT body scanning pending evaluation of efficacy. Historically, medicare has denied reimbursement for outmoded procedures rejected by the medical community. But medicare's action on CT scanning used efficacy and safety criteria to make a more controversial decision. And overall medicare policy supports strengthening the dependence of reimbursement on efficacy and safety. It is medicare's policy to restrict reimbursement for drugs to conditions of use approved by FDA. FDA's evaluation of devices under the Medical Device Amendments of 1976 does not yet provide a sufficient basis for medicare action. For advice on procedures and devices, medicare continues to rely mainly on the Office of Health Practice Assessment of the Public Health Service.

Although medicare policy links reimbursement to efficacy and safety, major problems remain. As discussed in section 1, information on the efficacy and safety of devices and procedures is insufficient for reimbursement purposes. These deficiencies range from inadequate clinical data through incomplete syntheses of existing information to the processes

used in making judgments. The task of evaluation is much beyond the present capability of the Office of Health Practice Assessment. Besides an inadequate information base, the Office has a small staff and no formal process for evaluating technologies. FDA labeling provides more available and useful information on drugs.

This fourth alternative suggests linking medicare's reimbursement for use of a technology to the information provided by alternative 1 and to the judgments about efficacy and safety reached under alternative 2. Medicare would not only refuse payment for a technology considered inefficacious or unsafe, but would also limit payment to conditions for which the technology was deemed efficacious and safe. The Office of Health Practice Assessment could continue to advise medicare. It could secure the relevant evaluations, digest them for medicare purposes, and point out areas needing further information. Alternatively, medicare could deal directly with any new office established.

Theoretically, the same procedure could apply to reimbursement under medicaid, but such a step might require amending the Social Security Act. Although medicare officials have already decided that the program has administrative authority to deny reimbursement for new technologies, medicaid administrators are less certain of medicaid's legal authority at the Federal level. States have the authority to deny medicaid reimbursement and have exercised that authority.

As a probable consequence of this fourth alternative, judgments about efficacy and safety would affect the use of medical technologies. To the extent that payment by medicare is important to hospitals, physicians, and patients, all three groups would have an incentive to follow the judgments made. As a result, this alternative could help prevent inappropriate and harmful technologies from being introduced, diffused, and used, and could reduce expenditures on them for medicare patients. At the same time, however, this alternative is less intrusive than directly prohibiting the use of a technology. Providers might use unapproved technologies, but would then simply forego medicare reimbursement.

Substantial changes in the medical care system could flow from this alternative. The traditional process of third-party payment by Government would change. Government has traditionally left decisions of appropriate technologies and conditions of use to practicing physicians. To the extent that Government reimbursement exerts leverage on providers, this alternative would restrict the use of technologies.

Implementing decisions at the local level to deny reimbursement would pose difficult technical problems. Medicare already transmits to its carriers and intermediaries instructions on particular technologies and conditions of use for which reimbursement should be denied. These medicare agents in turn have the responsibility of informing providers and enforcing the restrictions. Because of the magnitude of services involved, implementation depends primarily on the good faith of providers and secondarily on selected audits.

Billing practices, for example, make monitoring the use of specific technologies difficult. CT scans may be reported under the general category of radiological procedures. The present level of detail rarely indicates specific drugs or their conditions of use. In theory, Government agents adjust cost reimbursement for institutions to exclude costs of disallowed technologies, such as CT body scans. If implementation of this alternative made these adjustments too intricate and lengthy, the Government might choose to drop cost reimbursement and switch to payment by service, even in institutional settings.

This alternative could substantially lengthen the time required to introduce an innovation into medical practice. As discussed in section 1, the mere existence of information and judgments might influence the use of technologies. By denying Government reimbursement for unapproved uses of technologies, this alternative would give substance to those judgments. Providers would be reluctant to adopt procedures for which they and their patients could not receive payment. And the longer time required to introduce an innovation would apply to both efficacious and inefficacious technologies.

Linking medicare reimbursement to more systematic evaluations of efficacy and safety could occur only as a gradual process and over a long period of time. Clinical studies, syntheses, and judgments are all lengthy undertakings. A practical approach would be an incremental process of making reimbursement contingent on comprehensive evaluations as they become available. Or in the case of new technologies, the Government could mitigate the problem of delay by screening and permitting reimbursement for those with the potential to save patients for whom no efficacious technology exists. A new surgical procedure, for example, might be reimbursed for patients suffering from an otherwise fatal condition.

While a new technology is undergoing evaluation, medicare could pay for it only in designated locations. The choice of centers would have to take into account access for patients throughout the country.

These centers could provide data for evaluating the technology; their participation in controlled clinical trials could be a condition of their designation. These trials could generate data for analyzing efficacy and safety without widespread dissemination of the technology. This alternative might reduce innovation because it would make the process of innovation riskier for developers of new technologies. If other third-party payers followed medicare's lead and if this policy affected use and sales of a technology, innovation could become more risky.

Another consequence of this fourth alternative is that reimbursement would be withheld for patients covered by governmental programs, but not for other patients. Medicare and medicaid cover certain subgroups of the population because they have greater medical need or less ability to pay. Restricting reimbursement for these patients would probably result in their receiving different services from other patients because marry medicare and medicaid patients would be unable to pay for their own medical services. Such a consequence could protect these patients from harmful and inefficacious services, as well as prevent their receipt of efficacious and safe services. Other third parties such as Blue Shield are starting to make payment contingent on efficacy. To the extent that other insurers followed the same course, medicare and medicaid patients might not be restricted more than other patients with insurance.

The Department of Health, Education, and Welfare is already linking reimbursement and efficacy through administrative action, as discussed in chapter **6.** DHEW's decisions, then, may make congressional action superfluous,

Alternative 5: Expand regulation of capital expenditures to cover purchases of medical equipment regardless of setting or ownership.

Under the provisions of the National Health Planning and Resources Development Act (Public Law 93-641), capital expenditures over $150,000 are subject to certificate-of-need review only if made by specific medical care facilities. These facilities include hospitals and certain categories of ambulatory care facilities, but exclude private physicians' offices. Similarly, section 1122 of the Social Security Act applies to capital expenditures over $100,000 only if made by the same types of facilities. Therefore, unless State certificate-of-need laws authorize such regulation, purchases of equipment by physicians in private offices are not subject to review by planning agencies. At the end of 1977, the laws of only seven States covered physicians' offices.

These State laws encourage circumvention of the regulatory process by treating the same kinds of equipment differently, depending on ownership or setting. Physicians and other individuals may lease or purchase capital equipment, such as a CT scanner, place it near a facility that is regulated, and be exempt from review. To the extent that the national guidelines issued under Public Law 93-641 increase the stringency of criteria for regulated providers, the guidelines will further induce placement of equipment in unregulated settings.

Incomplete coverage of capital expenditures may foil the plans developed by local agencies. A planning agency may decide that a certain number of CT scanners is appropriate for its area and approve that number of applications from regulated providers. Purchase of scanners by other unregulated providers would counteract the local plan, but would lie outside the planning agency's jurisdiction.

This fifth alternative suggests amending current laws to cover capital expenditures over a certain amount, regardless of the ownership or setting where the equipment is operated. A planning agency would then have more complete control over the number and distribution of such equipment in its area. By expanding the regulation of capital expenditures to cover providers such as physicians' offices that are now exempt, the alternative would remove the present incentive for providers to place equipment in unregulated settings. This alternative would not give preference to one setting or form of ownership over another. Planning agencies could still set priorities among applications and exercise discretion over the placement of equipment. (Two bills, S. 2410 and S. 2551, that would so amend Public Law 93-641 are now before Congress.) The Social Security Act and the National Health Planning and Resources Development Act differ in the amount of the expenditure that triggers coverage. Legislation could make these amounts uniform, but that is an issue separate from this alternative,

The broadening of the planning provisions under this fifth alternative would necessitate arrangements for physicians to have access to available equipment. Since laws now generally apply to hospitals, any new problems of access would be limited to ambulatory patients; these patients could be transported between facilities. Many planners already include sharing of services in their criteria (see ch. 4). Ensuring access to equipment for physicians might require changes in the legal liability that a medical practice bears. A practice, which is now responsible for its own staff physicians, might otherwise become responsible for the actions of other physicians who are using the facility's equipment,

Implementation of this fifth alternative would increase the workload of the regulatory process, The total number of purchasers of equipment covered by

the law would increase substantially, with a probable rise in the number of certificate-of-need applications. Administrative costs of capital expenditure regulation would increase accordingly. To the extent that newly regulated purchasers of medical equipment required additional personnel time to apply for certificates of need, their costs would also rise. One should note that regulated providers already bear the cost of applications.

An increase in the level of regulatory activity could also slow the diffusion of new medical equipment. The implications for quality of care are unclear, since delay would affect efficacious and inefficacious technologies alike. Likewise, the effect on expenditures for a given technology is difficult to determine. The certificate-of-need process may deter some potential purchasers. Later purchasers of new products may benefit from lower prices as a result of competition or decreased manufacturing costs. Or they may face higher prices due to inflation, increased demand, or product development.

A related issue is the effect of this fifth alternative or any such regulation on total capital expenditures. Practical limitations of time and money require a minimum expenditure threshold for certificate-of-need review. But it has already been observed that regulated providers such as hospitals shift their capital expenditures to less regulated technologies. Such substitution is sometimes possible within the same category of equipment; some models of CT scanners sell for less than $100,000. This situation is part of the larger context wherein a new technology is not necessarily substituted for another. Rather the new are typically added to the store of existing technologies. This alternative, then, will not in itself limit either total capital expenditures on medical equipment or expenditures on the use of that equipment.

3. Financing Methods

The financing of medical care influences use of and expenditures for technologies through incentives to providers and patients and through restrictions on coverage and payment. The Federal financing programs, medicare and medicaid, have largely continued the reimbursement methods that prevailed in the private insurance field (see ch. 6). Payment by these programs to hospitals on the basis of costs incurred, and to physicians on the basis of charges, has resulted in an open-ended commitment by these Federal programs to finance the use of covered services.

In the course of financing medical care, public and private third-party payers have restricted the extent of coverage and payment. They have, in effect, defined the product for which they will pay. Medicare and certain private third parties in some cases have limited coverage to efficacious technologies. On that ground, medicare refused payment for CT body scans. (Setting maximum rates of payment for certain services are more widespread. Medicaid, for example, has placed ceilings on its reimbursement for drugs, and most third parties place some limits on their payment of physicians' charges.) Ironically, Federal financing—like health insurance in general—has encouraged the use of services such as CT scans, but not efficient methods in their performance or their substitution for other services. No restrictive mechanism such as a finite budget induces providers to make tradeoffs between increased information or benefit and increased costs from using technologies. On the contrary, financing methods reward with higher revenue those providers who perform additional services, regardless of their marginal value or efficient performance. As a result, providers have little incentive to choose among alternative procedures or to perform services efficiently. Prevailing third-party payment thus insulates providers as well as patients from the financial consequences of using technologies.

Contained in this section are two alternatives to address problems with current financing methods. Under the first, medicare and medicaid would continue to use costs or charges as the basis for reimbursement, but would base their rates on efficient methods of performing services. The second alternative would fundamentally change the payment method in order to create incentives for providers to become cost conscious in using and producing medical services. Although the alternatives in this section are mutually exclusive, either could be combined with alternatives from the previous sections on information and regulation.

> Alternative 6: For services paid by medicare and medicaid, establish rates of payment that are based on efficiency.

The Department of Health, Education, and Welfare has set limits on routine hospital operating costs and charges of drugs payable under medicare and medicaid, respectively. However, reimbursement limits on routine hospital costs are only very generally related to efficiency of operation. And with routine costs of a hospital day limited, hospitals have a strong incentive to allocate costs as much as possible to ancillary services, which are often not limited.

These policies give providers who receive cost reimbursement little incentive to be cost conscious in their services and production methods. As a result, governmental payments probably exceed those that would result from limits based on a tighter definition of efficiency.

Similarly, reimbursement to physicians is based not on standards of efficient operation, but on charges prevailing in a given area. Nor does governmental policy coordinate payments to hospitals and physicians' offices to ensure comparable payment for comparable services. Medicare, for example, could pay different amounts for the technical component of an ambulatory CT scan depending on the setting where it occurred, And the charge for that service in a physician's office is typically higher than its cost in a hospital.

Under this sixth alternative, rates of payment would be based on the basic costs necessary to operate a facility or piece of equipment at an efficient level. Soliciting bids from manufacturers might be required to lower purchase prices of equipment. To make payments consistent for comparable services that are based on charges in one setting and on costs in another, fee schedules would be developed for services paid by charges. Fees paid to physicians would also be based on costs using efficient methods of operation. To that basic amount would be added a predetermined profit margin to arrive at the allowable fee, This alternative could apply to all payers or all third-party payers, not just medicare and medicaid. In that case, the alternative would entail the establishment of national ratesetting for medical services.

Under this alternative, medicare and medicaid would not pay for inefficient methods of operation or for high profits. Rates could be reviewed to enable medicare and medicaid to take advantage of changes that had resulted in lowered costs, such as reductions in prices of equipment or improvements in methods of operation. Of course, changes in these factors could lead to increases in rates as well as decreases.

Under the assumption that medicare and medicaid payments exert a degree of leverage over providers, these federally set rates could encourage the performance of services in ways considered desirable by the Government. The relative rate structure for different settings, different tests, and different types of physician specialists could provide incentives favoring one over another. For example, the Government could establish rates for CT examinations and alternative diagnostic procedures, such as arteriograms, that would encourage the relative level of use of each test that was considered desirable. If all physicians were considered equally capable of reading CT scans, all could be reimbursed at the same rate. If some were considered capable and others not, reimbursement could be limited to those considered capable.

Considerable technical expertise would be needed to set, monitor, and review rates under this sixth alternative. For both hospitals' and physicians' rates, the Government would require experts with detailed knowledge of such factors as budgets, methods of performing services, and types of equipment. Also, to set fees and monitor costs, hospitals and physicians would have to adopt uniform methods of recording and reporting their costs. (Public Law 93-641 mandated the development of uniform accounting and reporting, and Public Law 95-142 required uniform reporting for institutions.) If payment under medicare and medicaid were based on the efficiency of services provided, hospitals would have to apportion costs to specific services, not to departments or functions as is currently done.

Whether the ratesetting described here would result in lower net expenditures on medical services is not clear. Rates would probably be lower for medicare payments, but total expenditures would not necessarily rise more slowly or decline absolutely. Other governments, such as those of the Canadian Provinces, have found that rates of use and therefore total expenditures have risen when rates of payment were held fixed. The costs of hiring the new technical experts required would also add to government expenditures. Despite the time and expense involved, this alternative would not necessarily lower payments under medicaid. Since 1972 when the law was amended, medicare's definition of reasonable costs for hospitals has been a maximum limit for medicaid payment; many States pay less. Medicaid's limits for physicians' services are also typically below those of medicare.

Certain adverse consequences might result if medicare rates paid to physicians were reduced below their current levels. For example, fewer physicians might be inclined to accept assignment for medicare patients (acceptance of medicare rates as full payment); the rate of assignment is already falling. In such circumstances, medicare patients with some financial means could pay the difference between physicians' charges and medicare's allowable fee, But patients with less ability to pay might have to rely on physicians with lower charges.

Overall, ratesetting entails detailed consideration of each service, the method of performing that service, and the profit margin. This course of action would be time-consuming and expensive for providers and governmental agencies alike. Implementing this sixth alternative might result in the Government's questioning in detail how medical services are provided. Furthermore, ratesetting would not affect the incentives of present reimbursement methods that encourage additional medical services, such as diagnostic tests, regardless of their marginal value.

Alternative 7: Fundamentally restructure the payment system to encourage providers to perform and use medical services efficiently.

Present retrospective payment of costs and charges and fee-for-service payment contain perverse incentives, as discussed in alternative **6.** These payment methods, used by public and private third parties and by self-payers, reward physicians and hospitals with higher revenue when they provide additional services. This result occurs regardless of whether the services substantially improve patient care or whether they are produced efficiently. Medicare, for example, pays for a CT head examination regardless of any other neurodiagnostic tests that have been performed and the information that may have been gained from them.

This study has identified the incentives of the present reimbursement system, but has not systematically analyzed possible changes in that system. This alternative, then, suggests a general restructuring of payment methods, but does not propose a definite substitute. The altered payment system would contain incentives for physicians and hospitals to provide appropriate care and to do so efficiently, instead of present incentives that conflict with these goals. Rather than control rates of payment for each service as in alternative **6,** this alternative would indirectly or directly fix the total revenue of a provider in advance of the delivery of medical care. Payment by cavitation (per person) would do so indirectly, while review of providers' budgets would fix that revenue directly.

The consequences of a restructured payment system would depend on the specific plan put into effect. Nevertheless, certain generalizations are possible. Limiting total revenue would both enable and force providers to make choices among alternative services and among alternative methods of performing those services. Within the predetermined revenue, a provider could choose which services to perform and how to perform them. With total revenue limited, for example, a hospital's administrator and physicians would decide whether to operate a CT scanner, how many scans to perform annually, which patients to scan, and how to combine CT scans with other diagnostic procedures.

Furthermore, physicians and hospital administrators rather than Government would make the decisions. The Government would set the cavitation payment or budget limit, but would not become involved with production methods, use, or payment for particular services. Providers could consider the cost implications of their actions, choose services to provide, and determine how to perform those services. The factors that physicians and hospitals weigh when making decisions would undoubtedly undergo great change. Additional services would no longer automatically increase their revenues and might even decrease their incomes by increasing their costs.

This seventh alternative could pertain either to Federal financing programs alone or to all payers of medical care. However, if only medicare and medicaid limited their payments, a provider could increase costs and charges and generate additional revenue from other third parties and self-payers. The alternative could also cover either hospitals or physicians. But some services that are performed in both hospitals and physicians' offices, such as ambulatory CT scans, are often substitutes for each other. If revenue were limited only for hospitals, one would expect payments to rise for nonhospital providers whose revenues were not limited. Although this alternative would clearly be most effective if applicable to all payers and providers, such an approach would represent a major policy decision. Private payers could, of course, follow any Federal lead. This alternative would also be compatible with national health insurance, for the Federal Government would then be the major payer of health care.

Calculating cavitation levels or revenue limits would require the responsible Government office to have much technical expertise. Experts would have to identify variables that cause costs to differ among providers or consumers and adjust payment levels accordingly. (Such efforts have not proved very successful in the past.) Governmental experts would also have to review rates periodically. The ways in which rates changed would greatly influence total medical expenditures. For example, a system of basing the rate of change on an indicator within the medical care system could simply accept and transmit increases with a lag of 1 year. Rate changes could be based on broader economic indicators, such as the GNP deflator, which would not necessarily be self-generating, But broader indicators might be insensitive to changes specific to the medical care sector.

Although the changed payment system would create an environment with different incentives, this seventh alternative would not necessitate substantial changes in the way providers are organized. Providers could continue to deliver medical care under current practice arrangements. Compared to the current situation, the new environment would enhance the competitive position and perhaps stimulate the growth of health maintenance organizations (HMOs) and other providers currently paid by cavitation, Such groups now compete for physicians, supplies, and enrollees with providers who gain more revenue from the provision of additional services. If cavitation payment or budget limits applied to all providers, all would have similar incentives and be sub-

ject to similar restrictions under the payment method. But the relative position of providers now paid by cavitation would be improved if others faced some limit on their total revenue.

The presence of different incentives would affect the kind of medical care delivered and expenditures on that care only over a long period of time. Similarly, any effect on the nature of medical care delivery and the strength of HMOs would occur over several years.

Changing payment to providers as described in this seventh alternative would be compatible with regulatory programs of certificate-of-need and utilization review, and might make these programs even more valuable than at present. Under this alternative, providers would have an incentive to underserve patients in order to stay within their budgets. Minimum standards of appropriate use might have increased importance in this new context. Utilization review under the PSRO program currently applies only to medicare and medicaid patients, as described in chapter 5. To prevent providers from economizing on service to nonmedicare and nonmedicaid patients, PSRO review could be broadened to cover all patients. Such an expansion of the PSRO program would represent a major policy decision and would substantially increase PSRO regulatory activities and administrative costs. Utilization review might also guard against the tendency of providers to consider costs exclusive of benefits in order to meet their budgets. Standards of appropriate use would thereby function as a counterweight to the possibility of increased cost consciousness by providers.