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Reimbursement

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INTRODUCTION AND BACKGROUND

Medicare and Blue Cross/Blue Shield, the largest government and private health insurance programs, respectively, pay for a substantial share of the Nation's total health care outlay. In 1978, for example, medicare financed 24 percent of all hospital care and 16 percent of all physicians' services. In fact, its payments represented more than 15 percent of all personal medical expenditures in the United States. In the same year, Blue Cross/Blue Shield paid for nearly 11.5 percent of all personal health care expenditures (84). Through financing, both programs can affect the rates at which new technologies are developed, diffused, and utilized, and at which inefficacious, outmoded, and unsafe services are phased out.

This chapter focuses on the medicare program and its reimbursement coverage process. Also included is a discussion of Blue Cross and Blue Shield and its reimbursement coverage process. The latter discussion is included because the national Blue Cross and Blue Shield Associations

and the affiliated plans (the actual administrative units, who are relatively autonomous and who receive guidance but not mandatory procedures from the national associations) represent the largest nongovernmental third-party payer in the Nation and because their processes of deciding on coverage of medical technologies for reimbursement are similar to medicare's.

Medicare is a nationwide, federally administered health insurance program authorized in 1965. It provides benefits for people over age 65, for certain individuals eligible for disability payments, and for certain individuals who need kidney transplantation or dialysis. The medicare program is a Federal program that is administered individually by each participating State government. Each State can use its own procedures for coverage decisions. Although medicare is not covered in this chapter, in concept, many of the arguments presented would apply equally well to that program.

THE MEDICARE COVERAGE PROCESS

Section 1862 of the Social Security Act mandates that medicare shall pay only for medical services that are "reasonable and necessary" for diagnosis, treatment, or improved functioning.¹ By granting Government officials the authority to determine which new and existing services² are eligible for reimbursement, this section of the law involves medicare in technology decisions. Medicare has refrained from establishing a definitive interpretation of the "reasonable

and necessary" language of the Social Security Act and relied on a loosely structured and decentralized mechanism to provide coverage guidelines.

The medicare program is administered in two parts: part A, financed by payroll taxes, provides reimbursement for services in hospitals, extended care facilities, and other institutions; and part B, a voluntary supplementary program, pays for physicians' services. Under the present coverage mechanism, the contractors who administer part A, fiscal intermediaries, and part B, carriers, of medicare bear the initial responsibility for identifying coverage

¹Sec. 1862.(a) Notwithstanding any other provisions of this title, no payment may be made under part A or part B for any expenses incurred for items or services (1) which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

²The Social Security Act also specifically excludes certain services from payment eligibility.

issues and determining reimbursement policy.³ Through the advice provided by their medical advisors, contractors make coverage determinations about the majority of new services that they identify (98).

When the contractors feel unable to make a judgment on a particular coverage issue, they submit the issue to one of 10 medicare regional offices. As a rule, referrals are made by carriers, who process physicians' bills, rather than by fiscal intermediaries, who process hospital bills. This is because under the cost reimbursement system, hospital bills generally are not examined for questions about the use of a particular technology. In fact, most hospital billing forms provide little specific information about the various elements of service (398,574). Although intermediaries, as well as hospitals, physicians, and the manufacturers of drugs and devices, may occasionally raise a coverage issue, carriers usually perform this function.

Coverage decisions by both contractors (239) and regional offices (398) appear to be based primarily on two related criteria: 1) the technology's stage of development, and 2) its general acceptance. If a new technology is perceived to have moved beyond experimental status toward full clinical application and to be accepted by the local medical community, then it is deemed "reasonable and necessary." These criteria, however, lack precise standards, and the contractors' procedures for considering them tend to be informal and highly variable. Thus, for example, a medical advisor may base a decision on immediate personal knowledge of a technology's stage of development and acceptance or may survey the literature and seek out the opinions of other medical consultants, local specialty society representatives, advocates of the procedure, and the advisors of other area insurance programs.

In addition, both contractors and medicare regional offices appear to show considerable variation in the priority they accord to coverage questions and their approach to handling them. Some regional offices will attempt to resolve

³Medicare contractors for part A deal with hospital services and contractors for part B deal with physicians' services.

many of the issues referred to them by seeking out the opinions of local contractors; others will tend to transmit such issues directly to the medicare central office (398,291). Similarly, within a region, some carriers will display far more initiative than others in identifying a coverage issue, pursuing information about it, and making a decision (398). As a result, the specific package of benefits for which medicare will provide reimbursement varies somewhat across the country, and there is no national standard for covered services.

When the contractor and medicare regional office are unable to resolve an issue, it is referred to the Health Care Financing Administration (HCFA).⁴ This agency, in turn, may request a coverage recommendation⁵ from the Public Health Service (PHS).⁶ Historically, PHS generated its responses through an informal and loosely structured procedure. Typically, one, two, or three professional PHS staff members assigned to the task researched a coverage question by attempting to survey the relevant medical literature and consult with appropriate experts. This process has been inherently unsystematic, because the small PHS staff has lacked the benefit of established channels of communications to medical specialty groups and to other PHS agencies such as the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) (98).

Within this ad hoc framework, PHS has traditionally applied four criteria to coverage recom-

⁴Reimbursement coverage questions are referred to the Health Standards and Quality Bureau (HSQB) in HCFA. Prior to the creation of HCFA, they were referred to medicare's Division of Provider and Reimbursement Policy.

⁵In 1977, the Administrator of HCFA and the Assistant Secretary of Health entered into an agreement which formalized the Public Health Service's role in providing coverage recommendations. Since the late 1960's, the medicare program's lack of medical advisors has resulted in an almost automatic referral of coverage questions to PHS, although occasionally HCFA has tried to group related issues together or resolve a matter which seems to warrant little attention because it has either been previously raised and answered by PHS or it concerns an apparently worthless service (e. g., colonic irrigation) or a well-established and accepted one.

⁶The current PHS unit providing coverage recommendations is the National Center for Health Care Technology (NCHCT). The Center was created by Public Law 95-623 in November 1978. Before the formation of NCHCT, the Office of Health Practice Assessment bore this responsibility. Previously, it was the function of the Bureau of Quality Assurance in the Health Services Administration.

mendations: 1) safety, 2) efficacy, 3) stage of development, and 4) acceptance by the medical community. Although, these criteria have recently been made more explicit⁷ through a PHS staff paper on coverage policy,⁸ they still lack precise definition.

PHS recommendations generally have not attempted to recommend specific indications for use of technologies. The PHS staff have maintained that coverage policies should be expressed in broad terms and questions of appropriate usage for a set of specific patient indications should be addressed by the practicing medical community and the Professional Standards Review Organizations. Thus, a PHS description of its coverage policy notes (98):

The coverage system cannot attempt to be an encyclopedic listing of which interventions to use in which circumstances nor serve as a kind of substitute for medical education and clinical training. Rather, the coverage system uses broad strokes to sketch the boundaries of accepted good medical practice, and leaves the fine-tuning of the system to the “back-end” mechanism, the Professional Standards Review Organizations (PSROS).

Recently, however, HCFA has shown some reluctance in accepting PHS recommendations and sought to issue guidelines which cite indications for use more often.

After the PHS staff develop a coverage recommendation, they send a memorandum to HCFA'S Health Standards and Quality Bureau (HSQB). This Bureau has usually accepted the

⁷Historically, these criteria have been developed and utilized implicitly (33).

⁸A PHS staff paper provides the elaboration of these terms (98):

1. Safety: What is the likelihood and severity of risk associated with the technology?
2. Efficacy: What is the likelihood that the technology will produce the desired health benefit? No distinction is drawn here between efficacy and effectiveness, although in other contexts, “efficacy” is used to mean the probability that a modality will produce a desired outcome under ideal circumstances, while “effectiveness” is used to mean that the desired outcome will result under average clinical conditions. The term “efficacy” as used here is intended to convey a hybrid of both meanings, since the data base for coverage decisions is sometimes derived from laboratory or clinical trial environments and sometimes from routine practice environments.
3. Stage of development: Has the technology moved beyond the experimental stage to full clinical application?
4. Acceptance by the medical community.

policy suggested by PHS and has issued appropriate guidelines to medicare regional offices and contractors (282). Because of the large volume of services involved, policy implementation depends mainly on the good faith of providers and on the threat of potential audits.

Cost and Efficacy

Although the cost of medical technology has focused attention on reimbursement, cost information has not been explicitly or directly considered in medicare coverage determinations. In a few cases, where PHS has concluded that a new technology is a modification of an existing intervention and offers little additional benefit, it has favored coverage but recommended payment at the same level as that for the established service. This type of judgment represents a weighing of marginal cost and marginal value, so it might be said that PHS has conducted implicit cost-effectiveness analyses (CEAS). The practice of paying usual and customary fees, however, does not easily accommodate such analyses.

Unlike cost, efficacy is one of the four criteria PHS has traditionally applied to coverage questions. Several recent PHS procedural changes have promoted more systematic examination of efficacy data: 1) the development of communication ties with NIH, FDA, and medical specialty societies; 2) the formal linking of FDA drug and medical device policies to PHS coverage determinations (98); and 3) the setting of a precedent in the computed tomography (CT) body scan decision to restrict coverage to uses that are supported by current evidence of efficacy (282), although the list of indications for those scans appears to include nearly every possible use (389).

The extent to which these procedural changes will ensure a greater emphasis on efficacy remains uncertain. Despite the CT body scan recommendation, PHS has generally not attempted to specify indications for use, contending it would do so only in the consideration of drugs or in an exceptional case involving a high-risk or a high-cost technology. Although it is committed to reflecting FDA's safety and efficacy rulings by following FDA's decisions on ap-

proved and contraindicated drug use, PHS exercises discretion in considering uses for indications on which FDA has not ruled. Further, drug coverage questions are not usually raised, because Medicare only pays for the use of drugs in hospitals, and it is difficult for fiscal intermediaries to identify individual hospital service components.⁹ Questions about medical equipment are far more typical, but the impact of relating coverage recommendations to FDA determinations is unclear, because the Medical Devices Amendments of 1976 are still in the process of being implemented (see ch. 8). Perhaps more importantly, adequate evidence of the efficacy and safety of devices and procedures is often not available (465), and in the absence of such evidence, technologies judged to be nonexperimental and accepted usually have received a positive coverage recommendation from PHS.

Application of efficacy criteria also is limited by the selected number of coverage questions that reach the PHS agenda.¹⁰ The current system, in which issues may be identified by fiscal intermediaries when they process hospitals' bills and by carriers when they process physicians' bills, is basically reactive. Identification of new services can be difficult, however, because information may be lost or obscured not only by classification into service code categories, but also by translation from provider to intermediary codes, although the tendency to attach a higher cost to a new technology serves as a major screening aid (399,569). Helen Smits, the Director of HCFA'S HSQB has observed (575):

A consistent method of coding diagnoses and procedures, consistently applied, is essential to any real "capture" of new technologies by reimbursement . . . Even when a single procedural code has been agreed upon and put into use, problems on variable coding are likely to persist and to make accurate application of coverage decisions very difficult.

Identification of a new hospital service is particularly problematic. This is because, as noted

⁹It is also extremely difficult to monitor drug use for approved indications.

¹⁰While judgments made by contractors and the regional office about acceptance and stage of development may be influenced by efficacy data, the focus appears to be more directly on stage of development and acceptance.

above, fiscal intermediaries generally do not examine hospital bills for coverage questions and the majority of billing forms¹¹ provide little information about the use of particular technology. Certificate-of-need requirements, end of the year or prospective reimbursement negotiation, and informal discussions between intermediaries and the hospitals in their area appear to alleviate this problem only partially.

Another way that a coverage issue may be raised is through the interaction of intermediaries and hospital administrators or staff when the hospital is planning to acquire or to offer a new service. Identification of large-scale, discrete, and potentially expensive technologies may be accomplished more easily through this type of interaction than it is through billings. Neither the extent nor the potential usefulness of such an identification method, however, was analyzed by OTA.

Even when a new service is identified, the coverage decision often, perhaps usually, will be made by the contractor or intermediary and will not be brought to the attention of HCFA or PHS unless a negative determination is legally challenged by a physician, hospital, or patient. For example, PHS has never been asked to make a judgment about the coverage of coronary artery bypass grafting (470), an expensive and widely performed procedure. In addition, the PHS coverage agenda is severely circumscribed by an almost exclusive emphasis on new technology. The one major exception to this pattern occurred in 1977, when PHS issued recommendations about 28 established procedures after Blue Shield had concluded they were outmoded or ineffective and should be excluded from routine reimbursement payments (431,432,433).

Currently, however, both HCFA and PHS are studying a number of possible changes in the Medicare coverage process that may increase the

¹¹ Because of the diversity of elements involved in surgical procedures, identification of a "new" surgical procedure may be particularly difficult. For example, David Eddy notes, "In surgery, it can be very difficult to identify when a procedure is "new" or sufficiently different from other procedures to require a new evaluation . . . frequently a procedure can be described only as a set of maneuvers, and these maneuvers can change in subtle but important ways" (167).

weight given to efficacy data, as well as formally introduce cost criteria. HCFA is examining several possible actions: utilizing cost as a coverage criterion, implementing regulations that would formally define the “reasonable and necessary” language of the Social Security Act, ¹² establishing a uniform service code, ¹³ and issuing more guidelines which relate coverage to appropriate indications for use. ¹⁴ At the same time, the new PHS coverage-recommending unit, the National Center for Health Care Technology (NCHCT) is considering utilizing three additional coverage criteria: conformity to health planning guidelines, relative efficacy, and cost effectiveness. Reservations have been raised about the introduction of the latter two criteria, however, because of methodological difficulties in measurement. As a result, the PHS coverage staff are currently awaiting the results of NCHCT’S experience with applying CEA in its comprehensive assessment activities. According to a PHS staff paper (98):

The chief difficulty is how to measure relative efficacy and cost-effectiveness in an operational way. If one is comparing the relative efficacy of two modalities, how much more efficacious must the more expensive or more risk, technology be in order to be “worth” the added cost or risk? The techniques for comparing relative efficacy and determining cost-effectiveness are less reliable than the methods for assessing safety and efficacy, and our experience in using the outputs of relative efficacy and cost-effectiveness studies as a basis for policy decisions is very weak. It would appear that some additional developmental work is needed before relative efficacy and cost-effectiveness can be applied routinely as criteria for coverage recommendations. One way to demonstrate and test the application of these two criteria would be to use them in the course of the large-scale evaluations

to which NCHCT will subject the high priority technologies. If the “bugs” appear to have been worked out in the mega-assessments, consideration would then be given to applying relative efficacy and cost-effectiveness more routinely in coverage decisions.

Coverage Reevaluation

Cost, safety, efficacy, and legal concerns have all contributed to the current reevaluation of medicare coverage decisions. Most important, perhaps, the rising cost of medical care has confronted policy makers with the need to contain health expenditures and rationally allocate resources. Increases in health care expenditures associated with both the enactment of medicare and the rapid diffusion and use of technology have generated additional interest in creating cost control mechanisms.

Although the overall impact of technological innovation on health care spending is unclear (17), it is apparent that economic incentives strongly favor the spread of technology (196, 528). Because medicare reimburses retrospectively, it provides an open-ended commitment to pay for covered services. Under medicare and some other third-party insurance, hospitals (the most expensive element of the health care system) are reimbursed on the basis of costs; physicians are reimbursed on the basis of charges; and patients are partly insulated from immediate actual costs. As a result, services may be utilized even when patient outcome benefits are marginal or uncertain (468).

The tendency toward utilization of services is also encouraged by other factors: competition among hospitals to achieve quality and prestige and attract patients and physicians; public demand for sophisticated technology; practitioners’ desire to do the most possible for their patients and to achieve a high degree of certainty in their judgments so as to avoid malpractice suits; physician specialization; and the stress on ancillary services (470,546).

Spiraling medical expenditures and their association with a reimbursement system that promotes technology development and use has encouraged Government officials to reevaluate medicare’s traditional social insurance orienta-

¹²The Office of the General Counsel has been asked to determine whether the “reasonable and necessary” language of sec. 1862 and the reference to “reasonable cost” in other parts of the legislation permit introduction of cost criteria into coverage decisions (292).

¹³HCFA’s Division of Provider and Reimbursement Policy has drawn up a set of draft regulations defining “reasonable and necessary,” and the Office of Policy Planning and Research also is in the process of performing the same task.

¹⁴A uniform code also may be used to produce a list of services that are covered (399).

¹⁵In recent months, HCFA has shown greater interest in issuing guidelines that cite indications for use.

tion. At the time of the enactment of the legislation in 1965,¹⁶ and in the years since, there has been an emphasis on accommodation with the existing health care system (191).¹⁷ This theme is reflected in the nature of the present coverage mechanism: the heavy reliance on fiscal intermediaries and carriers, the failure to formally define the “reasonable and necessary” language of section 1862, and the tendency for PHS to react favorably to the majority of coverage questions it has addressed. But as cost containment becomes an increasingly important objec-

tive,¹⁸ interest in medicare’s becoming a more selective purchaser of health services is rising (34). Within this changing perspective, cost-effectiveness information *would seem to possess* substantial appeal.

Reexamination of the medicare coverage system also stems from a growing awareness that technological innovation and health status do not always seem to be directly related and that the safety and efficacy of many technologies have not been adequately evaluated (238). There is interest in protecting patients from risky, ineffective, or unproven services. The result has been that coverage decisions are becoming more closely tied to available safety and efficacy information.

In addition, legal requirements have spurred PHS and HCFA review of the current coverage process. As the likelihood of more coverage denials increases, there is a greater need to establish a firmer legal basis for decisions (291,574).

¹⁶Feder suggests that reorganization was necessary for a shift in focus from social insurance to health policy (191). Several HCFA officials who were interviewed possessed a similar perspective.

¹⁷The Social Security Act states in sec. 1801:

Nothing in this title shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided

For a political history of medicare, see R. Harris, *A Sacred Trust* (278); T. H. Marmor and J. Marmor, *The Politics of Medicine* (381), and O. W. Anderson, *The Uneasy Equilibrium. Private and Public Financing of Health Services in the United States, 1875-1965* (25).

¹⁸Of course, the medicare legislation encouraged cost containment through physician self-regulation by originally establishing hospital utilization review committees in 1965 and later creating PSROS in 1972.

THE BLUE CROSS/BLUE SHIELD COVERAGE PROCESS

Cost considerations, along with safety and efficacy and legal concerns, in addition to leading medicare to reevaluate its coverage policies, have led nongovernmental insurers to reevaluate their coverage policies. Traditionally, these insurers’ interest in escalating health care costs has been moderated by their ability to respond by raising insurance premiums. But as the purchasers of health insurance—management, labor unions, and individual subscribers—have become more resistant to higher premiums (470), third-party payers have been increasingly confronted with the need to contain health care costs and become more selective purchasers of health services,

Blue Cross and Blue Shield, the largest nongovernment insurers, with over 40 percent of the Nation’s subscribers, have called for cost containment initiatives since the early 1970’s. Over the years, they have pursued a wide range of policies, including utilization review of length

of stay and level of care, health planning, benefit package designs that emphasize low-cost options (such as outpatient surgery), alternative delivery systems, consumer education, and coverage reevaluation (415). Like medicare, however, Blue Cross and Blue Shield traditionally have refrained from issuing many negative coverage guidelines. In part, this probably arises from a historical social insurance orientation, as well as Blue Cross and Blue Shield’s desire to: 1) remain competitive with commercial insurers, 2) fulfill the expectations of beneficiaries, hospitals, and physicians that services will be covered by insurance policies, and 3) forestall legal challenges that might result from denial of payment.

Blue Cross and Blue Shield’s treatment of coverage issues parallels medicare’s in many respects. Like medicare, Blue Cross and Blue Shield make the majority of coverage decisions through a decentralized and loosely structured process that places key emphasis on two cover-

age criteria: stage of development and acceptance by the medical community. Blue Cross and Blue Shield also lack a uniform national benefit package; interpretations of what qualifies as a covered service vary somewhat throughout the country. 19

Most individual Blue Cross and Blue Shield plan contracts exclude “care which is not a part of generally accepted medical practice” and “unnecessary or inappropriate care,” although the specific wording employed in different contracts varies (255). These criteria lack precise definition, however, so the medical advisors and their staffs possess considerable discretion in applying them, although coverage questions that are viewed as particularly important may be brought to the attention of a plan’s board of directors. Medical advisors may make judgments based on immediate personal knowledge or may survey the literature and consult with advocates of the procedure, local specialty societies, the county medical society, and other area insurers. If the plan functions as an intermediary for Medicare or an agent for Medicaid or the armed services CHAMPUS program, the medical advisor will generally review the coverage determinations of these programs. Similarly, the medical advisor will usually study the coverage recommendations of the national Blue Cross and Blue Shield Associations and other member plans, although he or she may or may not follow any previous rulings.

The national Blue Cross and Blue Shield Associations are a federation of 137 State and local nonprofit Blue Cross and Blue Shield affiliates. Power to make policy ultimately lies with the individual plans, but the national organization exercises considerable leverage through the prominence of its leadership and the ability to serve as a public spokesman for member plans (141,255,415). The national associations’ coverage recommendations are made by the Medical Necessity Program and the Medical Advisory Committee.

The Medical Necessity Program, developed in 1977 in conjunction with the American College

of Physicians, the American College of Surgeons, and the American College of Radiology, was designed to curtail reimbursement for outmoded, duplicative, or unproven procedures. According to a 1977 Blue Shield bulletin (433):

The Program is an effort to align the objectives of several national professional medical societies and of Blue Shield in improving the quality of care while simultaneously reducing the costs of procedures that are, in many instances, outmoded, redundant in combination with others, unlikely to yield additional information through repetition, or of unproven value.

Since the inception of this program, the Blue Cross and Blue Shield Associations have recommended discontinuation of routine payment for 68 surgical and diagnostic procedures and hospital admission battery tests (58,59,140,431, 432,433). While physicians may still order these procedures, they must provide written justification for their use in order to be reimbursed by plans that adopt the medical necessity proposals. Most plans appear to be accepting these recommendations, and it has been estimated that full implementation may result in annual savings of as much as \$200 million from limiting routine hospital admissions tests and as much as \$100 million from curtailing the use of 68 surgical and diagnostic procedures.²⁰

Moreover, the national Blue Cross and Blue Shield Associations make over 100 coverage recommendations a year through the deliberations of their Medical Advisory Committee. With the advice of medical specialty groups, the Medical Advisory Committee issues suggested coverage guidelines. Usually these recommendations concern new technology and are expressed in broad terms, but sometimes they specify indications for use. In addition, the committee serves as a clearinghouse for information about the coverage policies of each of the Blue Cross and Blue Shield plans.

The national Blue Cross and Blue Shield Associations consider only a limited number of coverage questions. Medical specialty group

²⁰In some areas where Blue Cross and Blue Shield plans are incorporated together, they share the same medical advisory staff; in other areas, they operate as separate organizations with separate staffs.

¹⁹While benefit package coverage variation allows responsiveness to local patterns of practice, it also raises the issue of equity.

representatives suggest which established procedures should be examined by the Medical Necessity Program, and the Medical Advisory Committee's agenda is largely determined by questions raised by plans when they seek the national associations advice.

Cost and Efficacy

Blue Cross and Blue Shield, like medicare, tend not to consider cost information directly in coverage deliberations. In a few cases, where a new procedure has been identified as a modification of an existing service which offers little additional benefit, however, payment for the new procedure has been fixed at the same level as that for the established technology. In addition, cost has traditionally been one of the factors examined in benefit package design. Recently, CEA was used in the development of a screening program when the National Cancer Institute contracted with the Blue Cross and Blue Shield Associations in 1976 to develop a model prepaid health service benefit package for cancer screening. Although the contents of this package originally were expected to be determined by the consensus decisions of a panel of experts, the program that eventually was designed was heavily influenced by the results of a CEA of cancer screening submitted by one of the consultants hired for the project (168,434). Moreover, the creation of the Medical Necessity Program has introduced an approximation of cost-effectiveness methodology in Blue Cross and Blue Shield coverage decisions, because cost consciousness has encouraged coverage determinations that are more closely related to judgments made by the national medical specialty societies.

Further, greater emphasis on efficacy data also has been promoted by Blue Cross and Blue Shield's sponsorship of an Institute of Medicine study of the CT scanner and subsequent recommendation that coverage be restricted to uses that the Institute found to be supported by current evidence of efficacy. Yet, the extent to which these changes indicate that more coverage decisions will be tied to efficacy information remains uncertain. Adequate evidence of the efficacy and safety of medical technologies often

is not available, and in the absence of such evidence, technologies judged to be nonexperimental and generally accepted usually receive positive coverage recommendations from both the plans and the national associations.

Currently, however, Blue Cross and Blue Shield are studying contract and coding changes that ultimately may facilitate the application of cost and efficacy criteria. Although Blue Cross and Blue Shield have their own procedure code, plans are mandated to use it only when they deal with national account business (group accounts in which some individuals live beyond the boundaries of an individual plan); other use is discretionary and many local affiliates choose to use other codes for their general subscribers. At present, however, the national associations are attempting to revise and update the code, a move which may make it more attractive to member plans and more useful for the identification of questions concerning coverage issues or inappropriate use of a technology. Moreover, the Blue Cross and Blue Shield Associations are considering inserting new exclusionary language in their national account contract and recommending a model contract exclusion clause to its local affiliates in order to develop a firmer legal basis for coverage decision.²¹ In recognition of this need, many plans have taken the initiative in recent years and developed more

²¹Thus, the Blue Cross Board of Directors and the Blue Shield Board of Directors will be asked to review and approve the following policy:

To recommend to the Boards that each Plan be encouraged to re-examine its contracts to assure adequate identification of medical necessity and experimental exclusions, and that the Boards offer the following language to each Plan for consideration.

"Medically necessary services or supplies provided by hospital, physician or other provider to identify or treat an illness or injury and which, as determined by the Plan, are:

- 1) Consistent with the symptom or diagnosis and treatment of the condition, disease, ailment or injury;
- 2) Appropriate with regard to standards of good medical practice;
- 3) Not primarily for the convenience of the member, his physician, or other provider;
- 4) The most appropriate supply or level of service which can safely be provided to the member. When applied to an inpatient, it further means that the member's medical symptoms or condition require that the services or supplies cannot be safely provided to the member as an outpatient.

Services and supplies which are *experimental or investigational* in nature; meaning any treatment, procedure, facility, equipment, drugs, drug usage, devices, or supplies not recognized as accepted medical practice or by the Plan and any of such items requiring federal or other governmental agency approval not granted at the time services were rendered."

specific exclusionary language for their contracts.^{zz}

A few plans in California, Pennsylvania, Michigan, Massachusetts, and New York also appear to have taken the initiative in developing a somewhat more systematic coverage mechanism. Perhaps the most sophisticated decision-making process has been adopted by California Blue Shield, which addresses a series of questions before making a coverage determination:

1. Is the procedure experimental or investigational?
2. Is it generally accepted?
3. What is its relative safety?
4. What does it cost?
5. Is there a procedure which costs less and achieves the same result?
6. Is it reproducible, i.e., can it be used by someone other than the original creator?
7. Is it generally available?
8. Does it make a difference in the management of patient outcomes or does it just serve an academic purpose?

Although stage of development and general acceptance remain the most important criteria, California Blue Shield has succeeded in formally

^{zz}For example, Washington, D.C., Blue Cross/Blue Shield issued the following statement in 1979 (59):

Group Hospitalization, Inc., and Medical Services of D.C. have always been denied claims for hospital and medical services or supplies which are not medically necessary. We're now adding a contractual provision to all non-group contracts which specifically excludes services or supplies which are not, in the judgment of the corporation, medically necessary for the diagnosis or treatment of an illness.

placing the concepts of cost and relative efficacy on its coverage agenda. In a few cases, where it has denied routine payment for a new procedure that it has determined costs more and achieves the same result as an existing technology, California Blue Shield has applied an approximation of CEA to its decisionmaking. Moreover, ultimate authority to make coverage determinations for the plan lies with the Medical Policy Committee, a 24-member group composed of physicians and 4 or 5 public representatives, which meets in a number of locations across the State and invites representatives of the local medical community and the appropriate specialty societies to attend its sessions. At least 2 or 3 weeks prior to the time the Medical Policy Committee meets, the medical advisor distributes an agenda book containing all the information that has been collected about the procedures to be discussed. As a result, the Blue Shield coverage has achieved a high degree of acceptance within the California medical community, and the meetings of the Medical Advisory Committee often serve as a public forum for the generation of consensus about a procedure. Thus, even when a decision is made not to restrict payment for a technology, the public discussion of its merits may result in discouraging its use. Further, the high visibility of the Blue Shield coverage process in California has augmented the State plan's ability to identify coverage issues, because the developers of new procedures tend to seek the advice of the Medical Advisory Committee before requesting reimbursement (165,537).

POTENTIAL USE OF CEA/CBA IN REIMBURSEMENT COVERAGE DECISIONS: GENERAL FINDINGS

Cost-effectiveness analysis/cost-benefit analysis (CEA/CBA) is based on the assumption that resources are limited and should be rationally allocated. Because it makes this assumption of limits and because it forces explicit consideration of alternatives for achieving goals, CEA/CBA would appear to be able to contribute important information to decisionmakers concerned with acting as selective purchasers of

health services. Yet its appeal for reimbursement officials seems severely tempered by the small number of well-conducted CEA/CBA studies available, methodological uncertainties of the techniques, and health policy makers' limited experience with their use. Moreover, the economic efficiency value embodied in cost-effectiveness information may conflict with a number of other values prevalent in our health

care system, including: 1) the practitioner's obligation to do the most for the patient, desire for relative certainty in making a diagnosis, and need to possess the freedom and flexibility to respond to the circumstances of the individual medical problem; 2) the patient's desire to receive a full range of medical care, regardless of ability to pay; 3) society's desire to encourage innovation in order to ultimately improve care; and 4) society's goals in terms of equity and other noneconomic values.

On the other hand, the methodology for efficacy and safety analysis is more widely accepted than that for CEA.²³ Efficacy and safety studies

²³For a discussion of the conflict of medical economic efficiency with efficacy, see W.B. Schwartz and P.L. Joskow, "Medical Efficacy Versus Economic Efficiency: A Conflict in Values," *N. Eng. J. Med.*, 1978 (548).

form part of a relatively more established health policy tradition, and the value of protecting patients from risky, unsafe, or unproven technology is less controversial⁽⁴⁶⁵⁾ than weighing marginal cost and benefit tradeoffs and not reimbursing for some potentially beneficial forms of care. For this reason, an approximation of the cost-effectiveness concept, in which cost-containment goals encourage stricter adherence to safety and efficacy data might be more appropriate and acceptable in reimbursement coverage decisions than would formal CEA/CBA. One of the problems with this approach, however, is that most technologies probably have some efficacy in some circumstances, and rational allocation requires choosing among alternative uses of technologies by considering marginal costs and marginal benefits and relative efficacy for a specific set of patient indications.

COST EFFECTIVENESS IN RATESETTING

In the last decade, the number of hospital ratesetting programs has increased rapidly. The central feature of this regulatory mechanism is the negotiation of hospital rates in advance of each operating year. Thus, Hellinger points out (294):

The key difference between prospective rate setting and conventional methods of reimbursement is that hospitals are not paid the costs they naturally incur, nor are they free to unilaterally adjust their charges to cover their costs or their own interpretations of their financial requirements; rather, they are paid at rates that are determined by another body and that are set in advance of, and considered fixed for, the prospective year.

Various ratesetting mechanisms, however, differ considerably in their structure and operations and in the methods and unit of payment they use to determine rates. For example, many programs have the power to set mandatory rates, whereas others rely on voluntary compliance. More than 20 programs are sponsored by Blue Cross, while 12 programs are funded by State governments, either through existing State agencies or newly formed independent commissions (154, 155,294).

Concern with the rapidly rising cost of health care has encouraged the growth of rate review mechanisms. In fact, Federal legislation has directly contributed to their development. Both the 1972 amendments to the Social Security Act (Public Law 92-603) and the 1974 National Health Planning and Resources Development Act (Public Law 93-641) provide for Federal funding of experiments in ratesetting. Moreover, escalating medicaid expenditures have prompted an increasing number of States to consider establishing a rate review system.

Basically, ratesetting agencies address the need to promote cost containment by encouraging hospitals to operate efficiently. By determining in advance the amount of revenue that will be available, they reward hospitals that keep actual costs below the established rates. Thus, Bauer points out (45):

The advantages seemed obvious; if a hospital could know its payment rate before it rendered its services, it would have the highest possible motivation to see that these services were produced in the most efficient manner, since its solvency would depend on keeping its spending within the limits of its anticipated revenues. The

hospital would have positive incentives for efficiency as well, since if it could produce its service more cheaply than the predetermined rate had allowed, it could pocket the difference.

In effect, then, the intent of rate review is to promote more efficient behavior by forcing hospitals to live within a fixed budget, identify and anticipate the costs of services and facilities, and make explicit decisions about the allocation of resources.

The record of ratesetting agencies thus far, however, is inconclusive (45,293,294). One significant limitation is that the lack of adequate data, performance standards, and methodology makes it very difficult to set rates of payment that promote efficiency. As Bauer notes, "The central issue is how to set rates in a manner that will neither underpay nor overpay, but will encourage each institution to increase the efficiency with which its services are provided" (45). Still another major problem is that ratesetting

programs tend to focus on hospital operating costs and do not concentrate on such other important areas as the costs generated by physicians.

Thus, it appears that use of CEA/CBA in rate review systems will have to await the development of more sophisticated ratesetting methods, more adequate data, and performance standards, and closer liaison with other organizations, such as health systems agencies. It may be that analysis concentrating on the net-cost end of the spectrum of analysis (e. g., cost per unit of service) is more appropriate for ratesetting. If so, ratesetting may be an area where increased numbers of CEA/CBA-like studies could be used. An interesting counterargument is that ratesetting could be based on the results of society-based CEA/CBAs and thereby would be less oriented to a narrower efficiency base and more toward social effectiveness.