Appendix D.—Selected Alternatives to Traditional Health Care Delivery

Introduction

Strategies for containing Medicare costs by changing the incentives for the adoption and use of medical technology were identified in chapters 5 through 8. Chapter 8 identified examples of alternatives to traditional health care delivery sites and organizations' that might stimulate competitive behavior by health care providers. The purpose of this appendix is to provide additional information on those alternatives. Available data on utilization by Medicare patients and costs to the program of these alternatives have been included in this appendix to illustrate potential data and evaluation needs. Assuming that a current goal of the Medicare program is to contain or reduce costs without compromising quality of care, it is reasonable to examine alternative sites and organizations of health care delivery for their potential in helping attain that goal.

Development of Alternative Sites and Organizations for Health Care Delivery

The precise reasons for the creation of alternative sites and organizations for health care delivery are difficult, if not impossible, to specify, although the causes of the proliferation of alternative sites and organizations for health care delivery clearly include economic and social forces. As the prices of medical care have soared, coverage of services by public programs such as Medicare and Medicaid and expanded coverage of services by private insurance companies have enabled a greater number of persons to obtain needed health services (135). Entrepreneurs responsive to financial incentives throughout the health care system have joined physicians and other health care providers in developing alternative sites and organizations of health care delivery. Many of the alternatives have developed as for-profit operations (325), and they have fostered competition in local markets. Freestanding ambulatory surgery centers and health maintenance organizations (HMOs), for example, developed under the influence of specific market conditions (e. g., overscheduled hospital operating rooms in the case of the centers and increased supply of physicians and Federal encouragement in the case of HMOs). Other alternatives have been developed to provide services at more convenient times and in more convenient locations for patients. Emergency care centers are an example.

Medicare itself has had varying impacts on the establishment of alternatives. Home health care agencies have proliferated since Medicare began covering home visits in 1966. Ambulatory surgery centers, on the other hand, developed without Medicare coverage, and although freestanding centers have received specific coverage since September 1982, the impact of the new coverage is unknown. Emergency care centers generally do not encourage Medicare patients to use them, and some even exclude Medicare patients except in life-threatening situations. The Medicare program was used to directly encourage the development of HMOs.

A major question with respect to alternative sites and organizations of health care delivery is whether the alternatives are less costly to patients, to the Medicare program, or to both. Some alternative sites (e. g., ambulatory surgery centers) may substitute for traditional hospital and physician office sites for some patients, while others (e. g., emergency care centers) may complement them. Covered sites of care may or may not save money, depending on the extent and appropriateness of use. As long as lower cost health services are *substituted* for more expensive ones, Medicare will save. If instead, the alternatives are used in addition to more expensive, traditional care, Medicare costs will rise. Potential cost savings for the Medicare program depend on the number of beneficiaries using any service, on the prices paid for medical technologies in various sites, and on the quality of the care produced. Quality is important in its own right. It is also important in economic terms, though, because lack of it may cost the beneficiaries and the program more in the long run.

Measurements of quality of care for alternative sites are controversial. For those sites of care and services specifically covered by Medicare, there are conditions of participation that providers must meet in order to receive payment. The conditions for freestanding ambulatory surgery centers, for example, specify that such centers must meet State licensing requirements and obtain accreditation by an appropriate association. Medicare conditions of participation have been criticized for concentrating on the structure and process aspects of quality measures (176) instead of on patient outcomes. In home health care, the Medicare conditions of participation have been important in developing quality assurance programs (176).

Costs of alternative sites for health care delivery are not easily compared. There are no published studies

[1]Prominent example'~ of "traditional sites or organizat ions are the independent community hospital, the solo, tee-ior-service physic ian and use of only hospitals for surgery

that account for differences in case mix and services rendered by freestanding emergency care centers, hospital emergency rooms or outpatient departments, or physicians' offices (2,325), One study on ambulatory care found slight differences in case mix between hospital outpatient departments and private physician office practices (200). Measuring differences in costs of various sites is also difficult, because hospitals, for example, do not use consistent methods of reporting costs, and, thus, do not accurately measure the true cost of ambulatory care (2). Measuring utilization of the alternative sites also presents problems. The customary measure is the visit, but differences in case mix, use of tests and procedures, and standby equipment and staff are not adequately accounted for by the visit measure (2).

The incentives for provider behavior will be changed by Medicare's new prospective per case payment system for inpatient hospital services (see ch. 6). Under the payment system based on Diagnosis Related Groups (DRGs), hospitals have financial incentives to decrease lengths of stay and substitute outpatient services for inpatient services. Increased use of outpatient visits might help prevent use of inpatient care, but the research evidence is mixed (33). Early discharges of hospitalized patients will probably increase the need for care in skilled nursing facilities (SNFs) and for home health care. Hospice care may also be affected by the DRG payment system, although in the absence of previous Medicare experience with hospices, interpretation of the evidence will be difficult.

The discussion below provides information on selected alternatives to traditional health care delivery. The first section discusses alternative sites of care, i.e., alternatives to inpatient care in hospitals and to primary care in physicians' offices. The second section describes two alternative organizations for health care delivery, HMOs and preferred provider organizations (PPOs), both of which may increase competition in the health field.

Alternative Sites of Health Care Delivery

Patients can obtain different types of medical care in a variety of locations. The sites described here are alternatives to inpatient care in hospitals and to primary care in physicians' offices. The discussion of each alternative site includes patterns of use, evidence on cost and quality of care, and effects of Medicare policy. Unfortunately, data vary in availability and quality, so comparisons are not always possible.

Alternatives to Inpatient Hospital Care

Entrepreneurs have reacted to the availability of money in the health care system by providing alternative sites for hospital care. In some cases, medical technologies are being moved from their traditional sites in hospitals to other locations. Certain surgical procedures have been moved from traditional hospital sites to ambulatory surgery centers. Hospital inpatient care for acute illness is being complemented, and, in some cases, replaced by home health and nursing home care. Palliative care for terminally ill patients has also been moved out of hospitals to hospices. These alternatives are described below.

Ambulatory Surgery Centers.—Units to accommodate ambulatory surgery were developed in the early 1970's in response to overcrowded operating room schedules and inconvenience to patients and physicians (125). Ambulatory surgery centers could not have been established without the technological improvement of fast-acting anesthesia and the practice of making patients walk soon after surgery (125). Some units are affiliated with hospitals and are located either in the hospitals or at other sites. Other units are not associated with hospitals. These units, known as freestanding ambulatory surgery centers, are often physician-owned. Surgical procedures that are appropriate to ambulatory surgery centers are those using general anesthesia but requiring only a few hours of postoperative monitoring of the patient. Patients are carefully screened. In recent years, third-party payers have accepted claims for surgery performed in these centers, and some now require that certain procedures be done on an ambulatory basis for coverage.

On September 7, 1982, Medicare changed its coverage of ambulatory surgery to encourage more patients and surgeons to use the less expensive freestanding ambulatory surgery centers (108). The purpose was to increase substitution of ambulatory surgery for inpatient surgery. The utilization of ambulatory surgery centers since that change is unknown. Yet there was sufficient concern about the possibility of adding to the surgical rate for Medicare beneficiaries that the General Accounting Office was requested to study utilization patterns in the first year of the new coverage policy (177).

Prior to the policy change, there was diversity in the age distribution of patients among freestanding ambulatory surgery centers, but there is no single source of reliable aggregate numbers of ambulatory surgical procedures by *age group* (325). From 1973 to 1980, surgical rates rose even more rapidly for the elderly

than for the general population in the United States (5). In 1967, 85.4 per 1,000 Medicare beneficiaries had surgery during their hospitalizations; but in 1972, the rate was 93.4; and in 1976, it was 104.9 surgeries per 1,000 beneficiaries (162). Again, improvements in anesthesia and in some procedures have reduced the risks of some types of surgery. More surgery is required, also, as people age and suffer from cataracts, cancer, and cardiovascular diseases.

Freestanding ambulatory surgery centers generally charge less than hospital inpatient or hospital outpatient surgery for most procedures. Clearly, inpatient surgery is more expensive, because patients must pay for a hospital stay of at least 1 day. In addition, freestanding ambulatory centers can charge lower prices because their construction costs are lower, they do not need some of the most expensive technologies available in hospital operating rooms, and their overhead is lower since many of the hospital ancillary services (e.g., food services) are not needed (124,428). It is likely that these fixed costs of the hospital setting will be spread among fewer surgical procedures, which will result in higher costs for hospital surgery.

Under Medicare, freestanding ambulatory surgery facility costs are covered for 100 specific procedures (an additional list of 50 has been proposed) in four groups to encourage use of the centers. Facility fees are prospectively set by the Health Care Financing Administration (HCFA), and the schedule is based on complexity of procedure with no beneficiary deductible or copayment. The least complex and least costly procedures (e. g., gastroscopy) are in Group 1, for which Medicare pays the center $231; the most complex and costly ambulatory surgical procedures (e.g., laparoscopy) are in Group 4, for which facilities are paid $336 (108). Physicians who accept assignment are paid 100 percent of reasonable charges for covered services. By statute, Medicare expenditures for ambulatory surgery must be less than they would be if the procedures were performed on an inpatient basis. HCFA estimated that this benefit would save $2 million for Medicare in its first year of operation.

Since hospital outpatient surgery is usually reimbursed 80 percent of costs with a 20-percent copayment, some hospitals with ambulatory surgery units might be at a disadvantage with regard to Medicare payment unless they elect to participate as though their units are fremtanding ambulatory surgery centers, i.e., accept the prospective fee schedule rather than cost-based reimbursement. To participate as freestanding units, they must establish *centers* that are physically, administratively, and financially independent from the rest of the hospital (108).

Quality of care in ambulatory surgery centers appears to be good. The centers have reported no deaths and lower complication rates than inpatient surgery (29,82,248). There is an accreditation association to advance their credibility to the public. In addition, *centers* that want to participate in Medicare must meet Medicare conditions of participation requiring that certain staff and equipment be available.

Home Health Care.—Continued growth in the home health industry is expected in response to the incentives under Medicare's DRG hospital payment system for shorter inpatient stays. The number of agencies providing home health care services has greatly increased since 1966 when Medicare began covering skilled nursing care and physical and speech therapy to homebound elderly people. The purposes of providing those services was to lower the hospital length of stay for acutely ill patients, thus cutting costs to the program.

The specific aspects of home health care have changed over time. Currently, the basic services are part-time or intermittent nursing care by or under the supervision of a registered nurse; physical, occupational, or speech therapy; medical social services; and part-time or intermittent services from a home health aide. Certain medical technologies that used to be administered only on an inpatient basis (e. g., intravenous antibiotic therapy) are now part of home health care (248).

Home health agencies may be licensed by the States, although the licensing requirement for Medicare participation was eliminated in 1980 with the passage of the Omnibus Reconciliation Act (Public Law 96-499) (207). Visiting nurses associations were among the first home health agencies (223). Other home health care providers are public health departments, hospitals, and independent agencies, both for-profit and not-for-profit, The hospital-affiliated home health agencies alone almost doubled between 1979 and 1982, when they numbered 450 and more than 720 respectively (207).

The number of home health care visits paid for by Medicare almost tripled between 1969 and 1980 (from 8.5 million to 22.4 million) (392). Studies of home health care in the 1970's seemed to indicate that home care made early discharges from hospitals possible. Recent studies looked at overall hospital use, but not readmission rates or length of stay (333), so the long-term effect of the early discharges and substitution of home care is not evident.

Home health care as a substitute for an extended hospital stay may be underutilized, although it appears to be used more often than SNFs by Medicare patients

(391). In 1980, home health agency services were used by 890,400 elderly and 67,000 disabled Medicare beneficiaries. Medicare reimbursed the agencies providing these services a total of $662.1 million (392). A General Accounting Office study of home health care demonstration projects showed mixed effects of expanded home health care on Medicare costs (333). Several demonstration projects have studied the effects of expanded home health care on patient outcomes: their results are also mixed (333).

The Omnibus Reconciliation Act of 1980 (Public Law 96-499) changed Medicare's home health care coverage by eliminating the remaining copayments, the limit on number of visits, and the hospitalization requirement. Patients must be homebound, under the care of a physician, and in need of skilled nursing or physical or speech therapy. Medicare Part A covers all home health visits unless a beneficiary has Part B coverage only. In the latter case, Part B covers the home health services (391).

Nursing Homes.—SNF care usually consists of skilled nursing care and rehabilitation services. Medicare covers 100 days of care in an SNF following an acute episode of illness. There is a required daily copayment of one-eighth of the Part A deductible ($44.50 in 1984) for days 20 through 100 in an SNF.

Not all SNFs are participants in Medicare. This situation exists in part because there is some financial risk posed by submitting claims to Medicare intermediaries that may deny payment, and in part because Medicare patients may require more intensive nursing care than the longer term chronically ill Medicaid and private-pay patients (106), Because there is limited access to SNF beds, Medicare patients have often remained in the hospital for extra days. For these patients, Medicare has paid as much as four times the necessary cost of patient care, possibly totaling $100 million to $900 million extra annually (106). By encouraging earlier discharges from hospitals, the DRG payment system will probably decrease these backup hospital days, estimated at from 1 million to 9.2 million annually (104). To alleviate the SNF bed shortage, some hospitals with extra beds are converting them into nursing home beds for long-term care (l03, 320). Hospital reporting requirements for skilled nursing beds are different from the reporting requirements for separate SNFs, so this bed conversion may not reduce costs to Medicare (278).

In 1980, 269,500 elderly and 9,300 disabled Medicare enrollees used SNF days (161). Yet Medicare pays only 2 percent of the total SNF industry revenues. In 1980, Medicare paid $339.3 million to SNFs for elderly beneficiaries and $13,5 million for disabled beneficiaries who were admitted. Table D-1 shows that discharges from and days of care in SNFs by Medicare enrollees have declined since 1969 (391), when a rigorous claims review policy resulted in retroactive denial of many claims and substantial loss of revenues for some SNFs (106).

Quality of care in nursing homes is variable. The Joint Commission on Accreditation of Hospitals accredits nursing homes. Medicare conditions of participation for SNFs are complex, State licensure requirements of nursing homes often have different definitions of "skilled" and "intermediate" care facilities than does HCFA. In many cases, nursing homes choose not to

Table D-l .—Use of and Reimbursement for Skilled Nursing Facilities (SNFs) Under Medicare by Type of Enrollee, 1969.79

	Discharges (thousands)		Days of care (thousands)		Reimbursements (millions)	
Year	Elderly	Disabled[a,b]	Elderly	Disabled[b]	Elderly	Disabled[b]
1969	367.9	NA[c]	14,467.0	NA	$277.3	NA
1970	277.4	NA	9,901.0	NA	200.3	NA
1971	237.8	NA	7,230.0	NA	164.7	NA
1972	218.0	NA	5,837.0	NA	140.8	NA
1973	237.2	2.2	6,372.0	51.0	157.7	$ 1.5
1974	262.8	8.0	7,185.0	216.0	197.4	6.7
1975	252.1	8.2	6,618.0	222.0	195.6	7.6
1976	255.6	8.7	6,808.0	232.0	219.4	8.6
1977	260.8	8.9	7,145.0	249.0	243.8	9.8
1979	269.6[d]	9.6	7,821.0	297.0	306.1	12.9
Annual compound rate of growth (%)	−4.2	3.6[e]	−8.4	4.9[e]	−1.6	13.5[e]

[a]Includes SNF discharges with at least 1 day of covered care under Medicare. Excludes stays for enrollees who had exhausted their SNF benefits and for whom no discharge record was received.
[b]Preliminary estimates.
[c]NA—Not applicable.
[d]Represents Medicare beneficiaries admitted rather than those discharged.
[e]Annual compound rate of growth computed only for 1974-77 because the 1973 figure does not cover a full year due to a change in eligibility policy, and the 1979 data represent slightly different information and thus are not included in the calculation.

SOURCE: C. Helbing, "Medicare: Use of Skilled Nursing Facilities, 1976-77," *Health Care Financing Notes*, U.S. DHHS publication No. 03021 (Baltimore, Md.: Health Care Financing Administration, 1980).

participate in Medicare because of the extra administrative burden of multiple regulations and requirements.

Hospices.—The hospice is a relatively new concept in care for patients with terminal illnesses. Until hospice care became available in this country, beginning in 1971, most terminally ill patients had been kept in hospitals and nursing homes. Terminally ill patients have usually undergone highly sophisticated treatments (e. g., radiation therapy, chemotherapy, and extensive surgery) without success. In hospices, such patients receive palliation of their symptoms and psychosocial care from a multidisciplinary team that includes physicians, nurses, social workers, clergy, psychologists and psychiatrists, dietitians, lawyers, and specially trained volunteers. Home care is one of the desirable aspects of hospice, for economic as well as psychological reasons, although it is not always possible. Furthermore, the use of many volunteers by hospices helps keep costs low. There are about 500 full-service and 500 part-service operating hospices and 80 in the planning stages (362). In 1982, Congress mandated in the Tax Equity and Fiscal Responsibility Act (Public Law 97-248) that Medicare cover 6 months of hospice care for terminally ill Medicare eligibles under Part A.

There is no experience to report on hospice use by Medicare beneficiaries, because hospice care is a new benefit. However, during congressional deliberations, the Congressional Budget Office estimated that potential users would number 268,000 in fiscal year 1984 but only about 12,000 would use the benefit that year (257),

Prices for hospice care have been based on the type of care and on costs from demonstration project hospices. The type of care is determined by how much nursing time a patient requires in a day. Costs differ between freestanding hospice units and hospital-based p e r p a - tient per year, on an aggregate basis (112).

Alternatives to Physicians' Offices

Primary medical care traditionally has been provided in physicians' offices. In recent years, however, alternative sites of primary care have been established in response to economic, social, and health factors. The supply of physicians has increased in many regions, so there is competition for patients. In addition, Medicare and Medicaid, among other Government programs, have provided funds for medical care for the elderly and the poor, thereby increasing the potential patient population. Patients' expectations have increased, and the U.S. population itself is growing older and needs more medical care. Two examples of alternative sites of primary care, hospital outpatient clinics and emergency care centers, are described below. Emergency care centers are also alternative sites for outpatient care.

Hospital Outpatient Departments. -Hospitals, particularly teaching hospitals, have long had outpatient departments. Yet in recent years, one of the ways hospitals have responded to financial pressures has been to expand services, including primary care in outpatient departments (136). The increased use of hospital ambulatory care in recent years is also due to limited access to private physicians for inner-city residents, increasing prevalence of chronic diseases, and greater expectations of patients for medical care from hospitals (2). Advances in medical technology have also resulted in the movement of some treatments from inpatient to outpatient settings (136,157,248). Visits to hospital outpatient departments by the elderly have been increasing, while the rest of the population has been using fewer outpatient visits (210).

Some hospitals are also establishing satellite clinics, i.e., decentralized sites where ambulatory care is available (142). Primary care clinics have been set up by many community hospitals throughout the country (40). Specialized clinics for the outpatient treatment of cancer patients have also been opened in some urban areas (263).

Over 10 percent of the physician visits made by persons 65 and older in 1978 were visits to hospital outpatient departments or emergency rooms (210). This was a 22.2-percent growth in outpatient department visits since 1973 for that age group. About one-third of these outpatient visits were to the emergency room, one-third to a physician in a clinic, and one-third to ancillary service referrals (210). The growth, especially in the ancillary service referrals and clinic visits, will probably continue after the implementation of Medicare's DRG payment system.

Hospital outpatient department and emergency room visits are combined in Medicare Part B statistics. In 1980, Medicare reimbursed $1.9 billion for outpatient services for about 7.5 million beneficiaries (392).

Medicare Part B pays 80 percent of reasonable charges for visits to hospital outpatient departments and emergency rooms. Part B beneficiaries must pay the initial deductible ($75 since 1983) and 20 percent coinsurance, just as they do for a physician office visit. Reasonable charges differ between physician offices and hospitals, and for outpatient visits, hospital charges are generally higher. Because hospitals must accept Medicare assignment, however, some patients may have an incentive to use hospital outpatient services instead of physician office visits.

Emergency Care Centers. —Emergency care centers are alternatives to hospital outpatient departments and to some emergency room care and to primary care in physician offices, Such centers, though generally equipped with some emergency technologies, do not treat life- or limb-threatening situations, so the name "emergency" may be misleading (325). They usually have more diagnostic technologies on location than a physician's office. Emergency care specialists and some family practitioners have opened emergency care centers to make medical care more accessible to patients who have no primary care physician or who cannot find a physician after hours, The centers have extended hours during evenings and weekends when physicians' offices are closed, and some are open 24 hours a day, 7 days a week. No appointments are necessary, so care is more convenient for some patients, although patients may not experience desired continuity of care.

Use of emergency care centers by the elderly has not been well documented. While one estimate of total visits to these centers was 12 million patient visits for 1982 (238), the elderly population is probably underrepresented. To keep costs down, most freestanding emergency care centers accept cash or credit cards only (325), so patients must be reimbursed by their insurance companies. This requirement may deter elderly and disabled patients with limited incomes from using the centers. Furthermore, most freestanding centers do not accept Medicare assignment, and this means more money out-of-pocket for elderly and disabled beneficiaries.

Emergency care centers usually compare their charges with those of hospital emergency rooms rather than with fees for physician office visits. This comparison is not necessarily a good one, because the care provided is often more like office than hospital care. Nonetheless, the National Association of Freestanding Emergency Centers estimates that center charges are 30 to 50 percent lower than hospital emergency rooms for comparable services (238). If an emergency care center is affiliated with a hospital, Medicare will reimburse for visits as though the center were a hospital department. If the center is freestanding, Medicare will pay as though the visit were a physician office visit (55). Hospitals must accept assignment to participate in Medicare, but physicians and freestanding centers need not. Thus, if elderly patients were informed about which centers were hospital affiliated or accepted assignment, they would be more likely to choose those centers over the other centers if total prices were comparable. A 1979 study showed that most of the emergency care centers' revenues came from private insurers or patients who paid directly, with only a small fraction coming from Medicaid and even less from Medicare beneficiaries (55). The 1983 followup, although limited in sample size, showed more centers accepting Medicare funds but some centers specifically excluding Medicare cases (250).

The National Association of Freestanding Emergency Centers has a policy of not judging the quality of care delivered in individual facilities but leaving that judgment to the patients (238). The centers are characterized as physician offices for quality review purposes by the physicians practicing in them. There are no licensing laws for freestanding emergency care centers in most States, although some States are trying to regulate them (239). If Medicare were to develop a special benefit program for emergency care centers like that for ambulatory surgery centers, more evidence of quality would probably be required in the conditions of participation.

Alternative Organizations for Health Care Delivery

Organizational differences among health care providers allow patients choices and increase competition in the health care market. This section describes two examples of alternative organizations that may increase competition among providers. Patterns of use, evidence on cost and quality of care, and effects of Medicare policy are presented for HMOs. PPOs are described only briefly because of a lack of information.

Health Maintenance Organizations

A defined set of physicians who provide services for a voluntarily enrolled population paying a prospective per capita amount is known as a group practice prepayment plan (GPPP). Some GPPPs have accepted financial risk for hospitalization of their patients and have become part of the competitive health care market known as HMOs. These organizations, thus, are both providers and insurers of comprehensive but specified medical services.

In a series of laws, the Federal Government has provided financial support for HMO development, including construction loans and mandatory access for HMOs (i.e., employers must offer an HMO health plan as an option for health insurance coverage). Not all HMOs have participated in these Federal programs because of the regulations imposed on participating HMOs (227), From 5.3 million enrollees and 142 plans in 1974, HMO enrollment doubled to 11.6 million enrollees in 269 plans in 1982 (85). Still, HMOs cover only about 5 percent of the U,S. population.

The growth of HMO and other GPPPs since the early 1970's has not been accompanied by a similar

growth in the number of Medicare enrollees joining these groups. By March 1982, 45 HMOs had cost contracts, 2 had normal risk contracts, and 8 had special experimental demonstration risk contracts with Medicare (392). Another 33 GPPPs were also participating under Medicare in less restrictive contracts (392). Just under 116,000 HMO members were Medicare enrollees as of March 1982, and about 515,000 Medicare enrollees were GPPP members (392). Thus, around 2 percent of the Medicare population is participating in an HMO or GPPP.

Under the Social Security Amendments of 1972 (Public Law 92-603), payment to HMOs for Medicare beneficiaries could be made under the usual cost-based method or under a risk-sharing contract. Most HMOs with Medicare enrollees are under a cost-contracting arrangement with Medicare in which they receive monthly interim payments based on their estimated allowed costs with a year-end adjustment to allowed costs (392).

As of March 1982, only two HMOs were under a risk contract in which its adjustment was compared with the adjusted average per capita cost (AAPCC) for its services. The AAPCC is the average per capita cost of providing services to the enrolled group of beneficiaries if they had been receiving fee-for-service care in their area (there are more specific actuarial and demographic factors that are used in calculating the actual AAPCC). If the HMO's costs are lower, it retains half of the savings above 80 percent of the AAPCC, for a maximum of 10 percent. Higher costs must be absorbed or carried over into the next budget year (392),

In September 1982, HCFA began funding five demonstration projects on a risk contract basis to see if significant numbers of Medicare beneficiaries could be enrolled in HMOS through aggressive marketing techniques and attractive benefit packages (97). These demonstrations have added significance in view of prospective payment provisions in the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248), and the establishment of Medicare's prospective hospital payment system using DRGs in the Social Security Amendments of 1983 (Public Law 98-21). One reason why HMOs have not actively sought to enroll Medicare beneficiaries may be that HMOs operate on a per capita payment basis, while their participation in Medicare necessitated significant administrative costs in order to conform to Medicare requirements for cost-based data. Medicare prospective payment would be in tune with HMO operations, and HMOs can be expected to be more aggressive in seeking Medicare beneficiaries. Another consideration in increasing HMO participation in Medicare is that beneficiaries need incentives to join HMOs, because many would have to change physicians and hospitals and would have less freedom of choice of physicians and hospitals in HMOs (145).

Analyses of Medicare beneficiaries' use patterns prior to their enrollment in three of the HCFA HMO demonstrations addressed the issue of whether beneficiaries sicker than the average Medicare enrollee would be attracted to HMOs or whether HMOs would recruit Medicare beneficiaries who had fewer medical problems on average (i.e., whether adverse or favorable selection from the standpoint of the HMO would occur) (97).

In two of the HMOs, which were closed-panel HMOs, pre-enrollment use rates of Medicare-reimbursed services were lower than the use rates of comparison group beneficiaries. In the third HMO, which operated much like an independent practice association (IPA) and which was the only significant provider of care in the area, there was no difference between the enrolled and comparison groups. The analysts studying the HMOs concluded that the circumstances under which enrollment occurred probably ruled out deliberate selection of healthier beneficiaries by the closed-panel HMOs and that the selection bias was probably on the part of the enrollees. As beneficiaries enrolling in the closed-panel HMOa probably had to give up their previous doctors and hospitals, these two HMOs may have enrolled Medicare beneficiaries who did not have close ties to their physicians. In the IPA-type HMO, most enrollees were probably receiving care from a physician who belonged to the IPA and therefore did not have to change physicians (97).

Interim results a study of one of the closed-panel HMOs (Oregon Region Kaiser-Permanente Medical Care Program) have shown that Medicare beneficiaries can be motivated to join HMOs through premium savings or increased benefits over those available from the fee-for-service sector and that there is a high level of acceptance of continued HMO participation (145). In regards to utilization, recruited Medicare members used hospital beds at a rate slightly higher than individuals over 65 previously enrolled in the plan. But the recruited Medicare members' rate of use was still much lower than the rate of all individuals over 65 in the same area—1,677 days per 1,000 members per year versus 3,142 days per 1,000 people per year. New members also used about 20 percent more office visits than old members of the same age group. The successful recruitment of additional members and increased utilization of services through the enhanced Medicare coverage provided in the demonstration projects led the authors to hypothesize the following: 1) prior Medicare coverage did not meet a significant

amount of need, and/or 2) those selecting HMOs were more likely to use services. These interim results also support the conclusion reached earlier in the pre-enrollment study (97) that the HMO did not recruit healthier beneficiaries.

The evidence on cost savings by HMOs centers around lower hospital utilization, although there is some evidence that physicians in HMOs use fewer tests and procedures than physicians paid on a fee-for-service basis (203). One of the reasons HMOs have not enrolled more Medicare patients may be that the aged and disabled require more costly care, including more physician visits and more hospitalizations, than a younger, healthier population.

Numerous studies have examined the structure, process, and outcome factors of quality for HMOs (205). In addition to the difficulty of defining and measuring quality, comparisons of HMO practices to fee-for-service practices are complicated by the insurance aspects of the former which change the financial incentives. The evidence on quality in HMOs does not support the contention that HMOs save money by providing lower quality care (204), Neither does the evidence support the suggestion of substantially better care in all HMOs (205). Thus, care in HMOs appears to be about equal in quality to that received through fee-for-service practices under conventional insurance coverage (429).

Preferred Provider Organizations

PPOs include a variety of organizational designs. Basically, PPOs are contract agreements between an insurer (or employer, if self-insured) and providers (physicians or hospitals or both) that give services at a reduced rate to the insured group. Patients are given a choice of seeing a physician from the PPO list at little or no out-of-pocket cost or seeing someone else and having to pay the difference in fees.

Incentives for the insurers to enter into PPO agreements include reduced cost because of the reduced rate and some control over utilization of medical technologies. This control comes from an agreement by the physicians to participate in utilization review and quality assurance programs. Physicians who overutilize tests and procedures potentially will be dropped from the PPO list. There are also incentives for physicians to agree to the discounts of 5 to 20 percent (191). First, insurance claims on a fee-for-service basis will be paid quickly and in full. Second, billing is easier for these patients. Finally, patient volume is guaranteed to be increased. Indeed, most PPOs have been initiated in areas where there are a very large number of physicians.

It is difficult to determine the number of PPOs because PPOs are agreements among entities, not entities themselves. Concentrations of PPOs are in Denver, Los Angeles, and San Francisco (100). MediCal (California's Medicaid program) is contracting with California hospitals, and a new law in that State allows contracting between hospitals and other third-party payers. Blue Cross and Blue Shield of Virginia is trying to set up a PPO in the Richmond area (147). Blue Cross and Blue Shield of Michigan is developing a PPO for Medicare recipients in Detroit under a HCFA grant (59). Data are not available on patient participation rates in PPOs. The agreements are too new to have generated much publishable data, and they are too diverse to use their data in comparisons with other physician organizations.

It is still too early to draw conclusions regarding cost and quality of PPOs. If patients choose the physicians offering reduced fees, the third-party payers may save. At the same time, these physicians have agreed to participate in utilization review and quality assurance programs. The design and implementation of these programs will be important to their acceptance by physicians and to their effectiveness.

Discussion

As noted earlier in this report, the original purpose of the Medicare program was to increase the access to medical care for the Nation's elderly population. Currently, the primary focus of policymakers is on cost containment. This appendix has described examples of alternative sites and organizations for health care delivery. These alternatives may represent future directions for Medicare cost-containment efforts.

Rational encouragement of the best alternatives would benefit the Medicare program and its enrollees. In order to decide which alternatives would provide the best quality of care at a low cost, comparisons of evidence on costs and quality are needed. This appendix has presented available evidence on patterns of Medicare beneficiaries' use of several alternatives and the available evidence on cost and quality. Clearly, more research and better data collection are needed. Definitional problems regarding quality, cost, and what constitutes a particular type of care exacerbate the paucity of comparable data (2,205,429).

Appendix E.— Decisionmaking by Medicare Contractors for Coverage of Medical Technologies

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Introduction

This study of decisionmaking by Medicare contractors was conducted for OTA to determine whether there is variation in decisionmaking by Medicare contractors (intermediaries and carriers) with respect to the coverage of particular medical technologies. The findings are based primarily on the results of a 1983 telephone survey of Medicare contractors.

Background and Objectives

Conventional wisdom holds that there is wide variation in the decisions made by Medicare contractors regarding the coverage of particular medical technologies. This variation stems from the absence of precise national policy about which medical care technologies are "reasonable and necessary" and, hence, eligible for reimbursement; the decentralized process by which Medicare coverage policy is promulgated and implemented; and the wide range of discretion allowed to individual contractors in making coverage and reimbursement decisions (54,143,353). Variation in Medicare contractors' interpretation of rules governing coverage of skilled nursing care has been documented (314). However, comparable information is not available to document the variation in contractors' coverage decisions about medical technologies.

Any attempt to change the economic incentives in the Medicare program by refining coverage policy in order to control or modify the adoption and use of medical technology, thereby constraining the growth of Medicare costs, ideally would be grounded on a better understanding of the way in which coverage decisions are currently made. This study was intended to assist in developing that information base by addressing the following specific objectives:

1. To determine the manner in which Medicare intermediaries and carriers identify new technologies and new uses of established technologies;
2. To determine the manner in which intermediaries and carriers monitor and implement national coverage decisions; and
3. To determine whether there is variation among intermediaries and carriers in Medicare coverage of specific technologies:
   a. by any type of technology (drugs, devices, and medical and surgical procedures); and
   b. by stage of development (experimental, new, and established).

This appendix presents the study findings. It includes a discussion of study methods, a description of findings with respect to reported coverage policies and factors associated with those policies, and a summary of conclusions.

Methods

The study requirements included drawing a sample of Medicare carriers and intermediaries, selecting the technologies for which specific coverage questions were formulated, developing and pretesting the questionnaire, and gathering and analyzing the survey data. The various aspects of the study methodology are presented in the following sections, along with a discussion of study limitations.

Sampling Plan

The sampling plan was developed to reflect characteristics of Medicare contractors that were hypothesized to influence their coverage decisionmaking. Adequate representation of both commercial insurance companies and Blue Cross/Blue Shield (BC/BS) plans was indicated because of the possibility that variation in claims processing between these groups might influence coverage decisions, Discussions with staff of OTA, the Health Care Financing Administration (HCFA), local BC/BS plans, and nearby hospitals suggested that intermediaries are more limited than carriers in their ability to identify new technologies or new uses of established technologies because of the restricted information provided by the hospital claim form. Accordingly, both carriers and intermediaries were represented. The potential variation in physician practice patterns among geographic regions required

a geographically balanced sample. To simplify the analysis, we preferred to avoid disproportionate sampling from fractions among these groupings of contractors. In the absence of firm information about the likely variation in decisionmaking among contractors, the sample size was governed primarily by the need to balance the contractors' characteristics specified above and the time and funds available for conducting the study. A total sample size of 60 contractors was deemed reasonable.

After determining the target sample size, the most recent HCFA intermediary and carrier directory was used as the sampling frame (385). Contractors in Hawaii and Puerto Rico were eliminated because of the time and expense involved in communicating with them. The HCFA Offices of Direct Reimbursement and Group Health Operations were also eliminated. (These offices serve as intermediaries and carriers for providers who bill HCFA directly, and, as such, have a unique national perspective. Because of pending organizational changes, however, information about their operations would provide little useful data on which to make policy recommendations.)

Random sampling resulted in an initial sample of 21 intermediaries and 39 carriers, whose distribution among Blue Cross/Blue Shield and commercial insurance contractors and geographic region is shown in table E-1. After telephoning to verify the names and addresses of persons in charge of government programs, a letter of introduction was sent to each sampled contractor, which described the purpose of the study and indicated that the program administrator would be contacted to schedule an interview.

Almost immediately, however, changes were required in the initial sample. Both the verification phone calls prior to mailing the introductory letter revealed that in many cases the HCFA directory was outdated. Some contractors no longer held HCFA contracts but were able to tell us who the current contractor was. In these instances, we replaced the prior contractor with the current contractor in order to maintain the geographic representativeness of the sample. Two other categories of sampled contractors performed no claims review functions: Railroad Retirement Boards, who contracted for review with a commercial insurance company; and home offices of large commercial companies, whose review functions were performed by field offices. Both were listed in the HCFA directory and given intermediary or carrier numbers, so there was no way to identify them in advance. When such contractors were identified, they were declared ineligible for inclusion in the sample because they were not engaged in claims review. They were subsequently replaced by another randomly selected contractor.

The final sample of contractors is shown in table E-2, which reflects the changes discussed above. Four contractors (all Blue Cross or Blue Shield plans) refused to participate. Their reasons for nonparticipation reflected extreme staff shortages and time pressures involved in the need to implement system changes demanded by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) and Social Security Amendments of 1983 (Public Law 98-21). Despite these changes, the representation of carriers and intermediaries remained about the same in both the original and final samples. Similarly, the distribution of contractors among HCFA regions remained about the same except that the minimum representation decreased in the final sample (i. e., only three contractors in the Denver region).

Questionnaire Development

A telephone-administered questionnaire was developed to elicit information about intermediaries' and

Table E.1 .—Distribution of initially Sampled Medicare Contractors

	Number of carriers		Number of intermediaries		
HCFA region	BC/BS	Commercial	BC/BS	Commercial	Total
Seattle	1	2	2	1	6
San Francisco	1	2	1	2	6
Denver	2	2	0	0	4
Dallas	2	2	1	0	5
Kansas City	3	2	1	1	7
Chicago	2	3	3	0	8
Atlanta	3	2	1	1	7
Philadelphia	2	0	2	0	4
New York	2	3	1	1	7
Boston,	1	2	1	2	6
Total	19	20	13	8	60

SOURCE: L K. Demlo, G T Hammons, J M Kuder, et al , "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies, " prepared for the Office of Technology Assessment, U.S. Congress, Oct 28, 1983

Table E-2.—Distribution of Actual Study Participants

HCFA region	Number of carriers		Number of intermediaries		Total
	BC/BS	Commercial	BCIBS	Commercial	
Seattle	1	2	1	1	5
San Francisco	1	2	1	2	6
Denver	2	1	0	0	3
Dallas	2	2	1	0	5
Kansas City	3	2	1	1	7
Chicago	2	2	3	0	8
Atlanta	3	4	1	0	8
Philadelphia	3	0	2	0	5
New York	1	1	1	2	5
Boston	2	1	2	0	5
Total	20	17	13	6	56

SOURCE L K Demlo, G T Hammons J M Kuder, et al , "Reporf of a Study on Decistionmaking by Medicare Contractors for Coverage of Medical Technologies, " prepared for the Office of Technology Assessment, U S Congress, Oct 28 1983

carriers' claims review processes, their uses and impressions of HCFA transmittals that update the Medicare coverage issues appendix, their methods for identifying technologies for which coverage may be questionable, and their policies with respect to covering certain technologies specified in the questionnaire. Potential questionnaire items were discussed with regional and national reimbursement experts. Two pilot tests were conducted, and additional questions were eliminated or refined in order to accommodate the 40-minute time limit.

The most complicated aspect of questionnaire development was identifying the technologies about which coverage questions were asked. This task was handled primarily by the physician member of the study team, in consultation with colleagues at the University of Iowa College of Medicine, medical consultants in insurance companies, and staff of OTA, HCFA, and the Office of Health Technology Assessment (OHTA) of the Public Health Service (PHS). In addition, recent HCFA updates to the coverage issues appendix, the Commerce Clearinghouse version of the appendix, and lists of studies completed or underway by OHTA were carefully reviewed.

As indicated by the study objectives, the technologies about which coverage questions were asked were chosen to represent a variety of types (drugs, devices, and medical and surgical procedures) at various stages of development (experimental, new, and established). This diversity was intended to raise different coverage issues reflecting questions about the extent to which these technologies are safe, effective, and generally accepted within the medical community. Developing a matrix of technologies for potential inclusion in the study proved to be difficult, however, since assigning individual technologies to these categories frequently required some arbitrary decisions. The dividing points between experimental, new, and established technologies are not clear-cut. Determining whether a procedure is medical or surgical may reflect personal biases about which medical specialty should be permitted to perform it, as well as its contribution to diagnostic v. therapeutic decisions, and its relative degree of invasiveness. The questionnaire was designed to include some technologies for which there is an explicit HCFA policy and some for which there is not, in which case Medicare contractors are expected to make their *own* determinations. Finally, Medicare coverage policy is constantly evolving. Even during this limited study period, there were changes in HCFA policy and its interpretation. The technologies included in the questionnaire are shown in table E-3. However, the sometimes arbitrary and fluid nature of the manner in which they are categorized should be noted.

Data Gathering

The interviews were conducted by a nonphysician senior member of the study team and two research assistants who were second-year graduate students in hospital and health administration. All interviewers consulted with the physician member of the study team and reviewed medical literature and the coverage issues appendix in order to become thoroughly familiar with the nature and uses of the medical technologies included in the study. Our intent was to interview a senior official from each Medicare contractor, who would be familiar with the overall processes by which claims were reviewed, as well as the contractor's specific coverage policies. In most cases, the respondent was a nonphysician administrator responsible for the Part A or Part B Medicare contract. Sometimes, physician consultants and nurse reviewers responded; occasionally, a conference call was held so that all three

Table E-3.Medical Technologies Included in Questionnaire

Technology	Type of technology	HCFA policy	Developmental stage	Use[b]
Intraocular lens implant following cataract removal	surgical' procedure	Covered	Experimental/new	Therapeutic
Chelation therapy with EDTA in the treatment of atherosclerosis	Drug/medical procedure	Not covered	Experimental	Therapeutic
Chelation therapy with EDTA in the treatment of rheumatic arthritis	Drug/medical procedure	Local option	Experimental	Therapeutic
Pacemaker device and its implantation for a patient with chronic second degree AV block of Mobitz type 11, with symptoms attributable to intermittent complete heart block	Device/surgical procedure	Covered[a]	Established	Therapeutic
Pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms	Device/surgical procedure	Covered[a]	Established	Therapeutic
Implantable chemotherapy infusion device, such as the "lnfusaid, " and its implantation for a patient with primary hepatic malignancy, such as hepatoma	Device/surgical procedure	Covered[a]	New	Therapeutic
Implantable chemotherapy infusion device for a patient with metastatic: cancer in the liver	Device/surgical procedure	Covered[a]	New	Therapeutic
External insulin infusion pump for a diabetic patient	Device	Covered[a]	Experimental/new	Therapeutic
Purchase of a home blood glucose monitor such as the Dextromete@	Device	Covered[a]	Established	Diagnostic
Continuous 24-hour monitoring of blood pressure using an automatic device (i.e., preset intervals not under control of patient for readings)	Device/medical procedure (interpretation)	Not covered (as of July 1983)	New	Diagnostic
Continuous 24-hour monitoring of blood pressure using a semiautomatic or patient-activated device	Device/medical procedure (interpretation)	Not covered	New	Diagnostic
Percutaneous transluminal coronary angioplasty (PTCA) for a single vessel procedure	Medical procedure	Covered[a]	New/established	Therapeutic
PTCA for two or more coronary arteries	Medical procedure	Not covered[a]	New	Therapeutic
Streptokinase administration at cardiac catheterization into a coronary artery to dissolve a clot in a patient with acute myocardial infarction (thrombolytic therapy)	Drug/medical procedure	Local option	Experimental	Therapeutic
External osteogenic stimulator for use in the treatment of a long bone fracture	Device/medical procedure	Covered[a]	New	Therapeutic
Chemonucleolysis (i.e., injection of the enzyme chymopapain or "Disease") in the treatment of a herniated disc	Drug/medical or surgical procedure	Local option	Experimental/new	Therapeutic
Electroencephalographic (EEG) monitoring during carotid endarterectomy	Medical procedure	Covered[a]	New use of established	Diagnostic
EEG monitoring during open heart surgery	Medical procedure	Not covered	New use of established	Diagnostic
Apheresis (therapeutic pheresis) or plasma exchange in the treatment of hyperglobulinemias such as a multiple myeloma	Medical procedure	Covered[a]	New or new use of established	Therapeutic

Table E-3.—Categorization of Medical Technologies Included in Questionnaire—Continued

Technology	Type of technology	HCFA policy	Developmental stage	Use[b]
Apheresis (therapeutic pheresis) or plasma exchange in the treatment of systemic lupus erythymatosis (SLE)	Medical procedure	Not covered	Experimental use of established	Therapeutic
Topical oxygen therapy for decubitus ulcers (e. g., Topox device)	Device/medical procedure	Not covered	Experimental	Therapeutic
Biofeedback therapy for intractable pain	Device/medical procedure	Not covered	New use of established	Therapeutic
PUVA therapy for psoriasis	Device/medical procedure	Covered[a]	New	Therapeutic

[a]Indicates that Medicare coverage is contingent on compliance with specified criteria or guidelines.
[b]"Diagnostic" includes use to monitor or guide therapy.

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

perspectives could be represented. The latter occurred at the suggestion of the respondent. The variation in respondents introduces the potential for bias; however, when the data were analyzed according to the position and discipline of the respondent, no systematic differences were detected.

Another source of potential bias was introduced by variation in the method by which answers were obtained. As noted earlier, the questionnaire was designed to be administered by telephone, In some instances, however, the respondent insisted on reviewing the questionnaire in advance and then responding by telephone or submitting the answers by mail. This occurred when the respondents were short of staff or when the contractor had a policy of only responding to self-administered mail questionnaires. Rather than lose the respondent, we reluctantly agreed to send the questionnaire in advance. Finally, in some cases, respondents were unable to respond to all the questions about technologies and preferred to check on coverage policy and provide the answers later, either in a followup telephone call or in writing.

Obviously, the respondents who reviewed the questionnaire in advance or who provided answers in followup contacts had the opportunity to consult the coverage issues appendix and provide the "correct" answer. We attempted to minimize this possibility in several ways. In administering the questionnaire, we were careful to emphasize that we expected variation to occur, that there was no "correct" answer, and that we were simply interested in ascertaining what the contractor's customary policy would be. In some instances, there was a general HCFA coverage policy, but in others, there was not. Ultimately, the data were analyzed according to the method by which answers were obtained; entirely by telephone interview (61 percent of the responding contractors); entirely by self-administration (14 percent); or by a combination of telephone interview and followup telephone or written response to questions that were initially unanswered (25 percent).

When the reported coverage policies for individual technologies were categorized according to these three general methods of response, a statistically significant difference was found for only one technology (the implantation of a pacemaker for a patient with sinus bradycardia without symptoms). For this technology, the responses derived entirely through a telephone interview indicated lowest adherence to HCFA policy, while those based on mixed methods showed highest adherence. The differences in reported coverage for a 24-hour, semiautomatic or patient-activated blood pressure monitor were almost statistically significant ($p = 0.079$). In this case, the responses to questions that were totally self-administered showed lowest adherence to HCFA policy, while those based on mixed methods again showed highest adherence. For all other technologies for which HCFA has established a coverage policy, the differences were not statistically significant at the 0.05 level and were about evenly divided among general methods of response. However, there remained a slight tendency (not statistically significant) for responses from contractors who utilized the combination method or self-administered responses to show greater adherence to HCFA policy. If one assumes that the responses derived entirely from telephone interviews are most likely to reflect actual contractor behavior (e. g., the reviewer simply made a decision based on the claim without bothering to refer to the coverage issues appendix), then the findings from this study are biased in the direction of underestimating deviation from HCFA coverage policy.

Study Limitations

The potential for bias stemming from the sample, variation in the position and discipline of the respondent, and the methods by which responses were ob-

tained was noted above. In addition, responses reflect the opinion of (usually) one respondent at one point in time about a limited set of medical technologies, Thus, the data would not reflect potentially different judgments about coverage policy made by different individuals within a single contractor organization or by a single individual at different points in time. Time and resource limitations precluded an indepth survey of all contractors in a manner that would illuminate both inter- and intracontractor variability in coverage decisions, categorized by a wide range of technologies and administrative and policy variables. Perhaps a more definitive study would be based on the submission of actual, identical claims to a sample of Medicare contractors and the analysis of variation in claims processing and decisionmaking; however, that was not our charge.

Despite the limitations of the current study, we believe that the findings are generally reliable and that the resulting information on coverage decisions of a sample of Medicare contractors should provide a useful framework for considering alternative Medicare coverage policies.

Findings

Although there was variation in reported coverage decisions by the Medicare carriers and intermediaries in our study, the processes by which claims are reviewed were quite predictable. The characteristics of the participating contractors are described below.

Characteristics of Participating Contractors

The 56 Medicare contractors (37 carriers and 19 intermediaries) included in the study reported fairly similar methods for processing Medicare claims. After an initial review of completeness, most claims pass through (potentially) three levels of review that reflect differing degrees of comprehensiveness, specificity, and clinical judgment and involve clerical employees, registered nurses, and physicians or some other health professional (pharmacist, podiatrist, occupational therapist, etc.) in that order. All but nine (16 percent) of the respondents utilized some automated screening procedures that vary in sophistication. The nine respondents without automated screening procedures were all intermediaries (contractors that process Part A claims), rather than carriers (contractors that process Part B claims). The most common computerized screens **flag cases** that exceed certain utilization parameters (specified numbers of hospital days, office visits, lab services, nursing home visits, etc.), claims requesting payment for noncovered services, incompatible diagnostic and procedure codes, and claims involving diagnoses, procedures, or providers which are automatically submitted to medical review by physicians.

The referral of claims to registered nurses is generally based on rather clear-cut screening and referral guidelines, recorded in policy manuals and employed either by clerical workers or automated review processes. All but two contractors (4 percent) also have established criteria to assist nurse reviewers in determining when to refer a coverage question to a medical consultant. Referral guidelines often reflect cases that have been troublesome in the past, as well as claims for technologies for which there is no prior claims experience, so there is no precedent for making a coverage determination. Some guidelines specify particular conditions or technologies for which review by a physician consultant is always required, such as bypass surgery, pacemaker implantations, computed tomography (CT) scans, and cases involving enteral and parenteral feeding.

Physician consultants utilize their own knowledge of medical practice and the scientific literature to resolve many coverage questions. Institutional sources of information utilized by consultants in making coverage determinations are shown in table E-4. The HCFA regional office, colleagues in other insurance companies or BC/BS Plans, and State and national medical and specialty associations are most frequently consulted. Professional Standards Review Organizations (PSROs) (now utilization and qualily control peer review organizations (PROS)) are least frequently used. Other resources include “inhouse” peer review panels, publications of the Food and Drug Administration (FDA), drug manuals, informal medical consultation, and policies established for private programs whose claims are also processed by the Medicare contractor. The responses were very similar for both commercial insurance companies and BC/BS plans, except that the “Blues” were much more likely to turn to national insurance associations (in this case, the Blue Cross and Blue Shield Association), while commercial insurers were more likely to rely on State or national medical or specialty associations. The responses for intermediaries and carriers were also quite similar, except that intermediaries were more likely than carriers to rely on information from PSROs, HCFA regional offices, national insurance associations, and manufacturers. These differences were not statistically significant, however.

Most contractors report that they learn about new technologies for which coverage questions might be raised prior to the actual submission of claims through inquiries from providers and manufacturers, drug and

Table E-4.—Sources of Information Used by Medical Consultants in Making Coverage Decisions

Sources	Percent of consultants using source: Yes	No
Colleagues in another insurance company or BC/BS plan	78.6	21,4
HCFA regional office	87.5	12.5
University medical center	44.6	55.4
PSRO (PRO)	26.9	73.1
National insurance association	37.5	62.5
State or national medical or specialty association	75.0	25.0
Drug or device manufacturer	53.6	46.4
Other	51.0	49,0

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983

device approval lists from the FDA, and HCFA announcements. Once claims are submitted, new technologies are identified because of the absence of code numbers or the presence of codes that are not recognized by the claims reviewers, A few contractors conduct extensive research to assist in identifying and making coverage decisions for such claims, utilizing in-house review panels, specialists in nearby medical colleges, and medical journals. The majority, however, assume a more passive role. Similarly, the majority are reasonably well satisfied with existing methods for identifying new technologies and report that this is not a big problem for them. Some mentioned a need for greater cooperation between national medical and insurance associations and governmental agencies, as well as faster turnaround on coverage decisions, once questions are raised. There were no noticeable differences between intermediaries and contractors in these responses.

The volume of claims processed by the study contractors varies widely. During the March to January quarter of 1983, the total number of Medicare claims processed ranged from 18,000 to 4,155,000 claims per contractor, with a mean of 854,741,

Reported Coverage Decisions

The basic data reflecting reported coverage decisions for specified medical technologies are shown in table E-5. The columns headed "covered" and "not covered" include clear-cut responses with no associated qualifications or criteria. To estimate the frequency with which contractors cover individual technologies, the reader should combine the responses from the first and third columns. The latter include responses indicating that coverage would be dependent on compliance with specified criteria or guidelines, discussed in more detail below. Whenever possible, respondents were limited to these first three categories, even if that required a followup phone call to determine actual coverage policy. The fourth, fifth, and sixth columns (referral to the coverage issues appendix, to a physician consultant, or to the HCFA regional office) may be viewed as "last resort" responses. They were used in instances where the respondent had never heard of the technology, or had never seen a relevant claim, and had no precedent for making a decision other than to refer to one of the three sources of assistance. The number of responses is sometimes less than the total number of study participants. Since the same questions were asked of both carriers and intermediaries, there were some instances when the question was not applicable. For intermediaries, this was especially true for questions about durable medical equipment for home use. When a question was not applicable, the response was coded as "missing data" and excluded from the reported responses.

Table E-5 reveals some instances of near unanimity or high levels of agreement in coverage decisions—particularly for intraocular lens implant following cataract removal (98.2 percent covered), the use of chelation therapy in the treatment of atherosclerosis (87.0 percent not covered), and the use of topical oxygen therapy for decubitus ulcers (86.3 percent not covered). However, there are also examples of considerable variation in coverage policies—particularly for a pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms, an implantable chemotherapy infusion device for a patient with metastatic liver cancer, an external insulin infusion pump for a diabetic patient, and streptokinase administration at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction. These responses and their implications are perhaps better presented in table E-6, which categorizes them according to HCFA coverage policy.

Table E-5.—Reported Coverage Decisions for Specified Medical Technologies

Technology	Covered	Not covered	Covered with qualifications	Referral to coverage issues appendix	Referral to physician consultant	Referral to HCFA regional office	Number of responses
Intraocular lens implant	98.2%	—	—	1.8%	—	—	55
Chelation therapy: atherosclerosis	—	87.0%	3.7%	7.4	1.9%	—	54
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	7.5	1.9	3.8%	53
Pacemaker: chronic second degree AV block	70.9	—	20.0	1.8	7.3	—	55
Pacemaker: sinus bradycardia without symptoms	13.0	44.4	29.6	1.9	11.1	—	54
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	3.8	11.5	—	52
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	3.8	13.5	1.9	52
External insulin infusion pump	10.6	46.8	27.7	4.3	8.5	2.1	47
Home blood glucose monitor	11.8	7.8	72.5	7.8	—	—	51
24-hour blood pressure monitoring: automatic	8.3	52.1	27.1	4.2	6.3	2.1	48
24-hour blood pressure monitoring: semi-automatic or patient-activated	4.2	77.1	8.3	6.3	4.2	—	48
PTCA: single vessel procedure	61.1	3.7	25.9	9.3	—	—	54
PTCA: 2 or more coronary arteries	19.2	51.9	19.2	3.8	3.8	1.9	52
Streptokinase at cardiac catheterization:	30.2	45.3	15.1	1.9	5.7	1.9	53
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8	—	—	51
Chemonucleolysis: herniated disc	64.0	10.0	14.0	2.0	8.0	2.0	50
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	6.0	2.0	—	50
EEG monitoring: open heart surgery	15.4	71.2	9.6	1.9	1.9	—	52
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7	—	—	53
Apheresis: systemic lupus erythymatosis	18.0	60.0	14.0	4.0	4.0	—	50
Topical oxygen therapy: decubitus ulcers	7.8	86.3	5.9	—	—	—	51
Biofeedback: intractable pain	9.3	55.6	31.5	1.9	1.9	—	54
PUVA: psoriasis	38.5	5.8	50.0	—	1.9	3.8	52

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al. "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

Technologies Covered by HCFA

The technologies for which HCFA explicitly provide coverage[1] have a higher percent of responses indicating unqualified coverage than those in any subsequent coverage category (see table E-6). The implantation of an intraocular lens provides an exception to HCFA's general policy of not covering experimental or investigational items or services. Although FDA still considers intraocular lenses to be investigational, Congress directed FDA to study them without interfering with their availability to patients. Lens implantation is the only technology included in this study for which almost all respondents (about 98 percent) indicated a policy of unqualified coverage. For the remaining technologies in this category, most qualified responses reflect the contractor's policy of assuring that HCFA's coverage criteria are met, even though the questions were phrased so as to leave little doubt about their eligibility for coverage. Because of the publicity surrounding pacemakers, many contractors automatically submit all such claims to medical consultants for in-depth investigation prior to payment. If the qualified and unqualified coverages are combined, close to 90 percent of the respondents indicated that they approve coverage for the technologies that are explicitly covered according to HCFA policy. The one exception was electroencephalographic monitoring during carotid endarterectomy, which reportedly would not be covered by about 14 percent of the contractors.

[1]One may argue that even for these technologies, HCFA specifies some criteria or guidelines for approving coverage. For example, the services must still be reasonable and necessary for the individual patient. With respect to pacemakers, HCFA has specified three groups of medical indications that: 1) may be covered without further claims development, 2) require more specific claims information, or 3) would generally result in denial. Furthermore, final coverage determination of a claim for pacemaker implantation must "take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient." However, our phrasing of the questions in the first grouping was such that their eligibility for Medicare coverage was intended to be obvious.

Table E-6.—Reported Coverage Decisions by Medicare Contractors

Technology/HCFA coverage policy	Decisions/policy of contractors: Covered	Not covered	Covered with qualifications	Refer for advice
HCFA explicitly covers:				
Intraocular lens implant	98.2%	—	—	1.8%
Pacemaker: chronic second degree AV block	70.9	—	20.0%	9.1
PTCA: single vessel procedure	61.1	3.7%	25.9	9.3
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	8.0
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7
HFCA covers with qualifications:				
Home blood glucose monitor	11.8	7.8	72.5	7.8
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8
PUVA: psoriasis	38.5	5.8	50.0	5.8
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	15.4
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	19.2
External insulin infusion pump	10.6	46.8	27.7	14.9
No explicit HCFA policy—contractor decides (local option):				
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	13.2
Streptokinase at cardiac catheterization: AMI	30.2	45.3	15.1	9.4
Chemonucleolysis: herniated disc	64.0	10.0	14.0	12.0
HCFA denies, but not explicitly:				
Biofeedback: intractable pain	9.3	55.6	31.5	3.7
PTCA: two or more coronary arteries	19.2	51.9	19.2	9.6
Apheresis: systemic lupus erythymatosis	18.0	60.0	14.0	8.0
HCFA explicitly denies:				
Chelation therapy: atherosclerosis	—	87.0	3.7	9.3
Pacemaker: sinus bradycardia without symptoms	13.0	44.0	29.6	13.0
24-hour blood pressure monitoring: automatic policy effective 7/83)	8.3	52.1	27.1	12.5
24-hour blood pressure monitoring: semiautomatic or patient activated	4.2	77.1	8.3	10.4
EEG monitoring: open heart surgery	15.4	71.2	9.6	3.8
Topical oxygen therapy: decubitus ulcers	7.8	86.3	5.9	—

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

The second category of technologies in table E-6 includes those for which HCFA has delineated criteria that must be met in order for coverage to be approved and for which our descriptions of the procedure were less specific than in the first category. The qualifications associated with approving a claim for the purchase of a home blood glucose monitor, the use of an external osteogenic stimulator in the treatment of a long bone fracture, and the use of PUVA for psoriasis consistently reflect the application of criteria specified in the coverage issues appendix. If the qualified and unqualified coverages are combined, from 84 to 88 percent of the respondents approve coverage for these three procedures, although some approvals may be granted without ascertaining whether the specified criteria are met.

The responses pertaining to the coverage of infusion devices require somewhat more interpretation. Currently, the only pertinent national coverage instructions are those in section 60-9 of the coverage issues appendix and in section 2100.5 of the Medicare carrier's manual. The coverage issues appendix provides that infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for home use. The Medicare carriers manual provides that reimbursement may be made for supplies necessary for the effective use of durable medical equipment, citing as an example tumor chemotherapy agents used with an infusion pump, as long as the drug or biological used with a pump is reasonable and necessary for the patient's treatment. The state of the art of infusion pump technology has changed considerably since these policies were developed. They have been interpreted by HCFA to include an implantable pump such as that manufactured by the Infusaid Corp. (referred to in the questionnaire), even though the policies were not developed with that technology in mind, PHS is examining issues related to the coverage of infusion pumps, including chemotherapy and insulin devices. HCFA is postponing the issuance of revised chemotherapy guidelines until those studies are completed. The responses to our questionnaire items reflect this uncertainty.

The respondents were most likely to cover an implantable chemotherapy infusion device, such as the "Infusaid," and its implantation for patients with primary hepatic malignancy, such as hepatoma. They were less likely to cover the same device for a patient with cancer metastatic to the liver. They were least likely to cover an external insulin infusion pump for a diabetic patient; of the three technologies, the responses cover the total range of response options—perhaps more so than for any other technology considered to this point. The circumstances of coverage for the chemotherapy infusion device reflected FDA approval status of the drug to be administered, as well as the condition of the patient. For example, one respondent indicated that the device would be covered for a patient with metastasized liver cancer only if the liver were the key to survival and at least a 6-month survival period were likely. Criteria were also specified for coverage of an external insulin infusion pump, including patient condition (e. g., a "brittle diabetic"), case-by-case review to assure medical necessity rather than simply convenience, and a multidisciplinary assessment of diet and exercise programs and patient motivation. One respondent indicated that the same criteria would be applied as for a home blood glucose monitor.

"Local Option" Technologies

Technologies are included in the coverage issues appendix only if they have presented difficult coverage questions for Medicare contractors, who generally would have submitted them to a HCFA regional office, and, eventually, to the central office in Baltimore for a national coverage determination. HCFA policy holds that individual Medicare contractors should make coverage decisions for all technologies that are not mentioned in the coverage issues appendix. In other words, their coverage status is determined by "local option.'" The technologies included in this study that fall into the "local option" category all involve the use of drugs, which in turn, requires that contractors refer to FDA policy in making Medicare coverage decisions. These technologies are included in the third category in table E-6.

Although the drug mentioned in our questions about chelation therapy (endrate or disodium EDTA) has been approved by FDA, the labeling indications do not mention its use for rheumatoid arthritis. About 81 percent of the respondents approve coverage of streptokinase administered at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction, as well as chemonucleolysis injections in the

[2]This distinction between technologies for which coverage is specified in the coverage issues appendix and those for which coverage is expected to be a matter of local option is overly simplistic and glosses over an important source of ambiguity and confusion in HCFA policy. Not all technologies that are not mentioned in the coverage issues appendix are expected to be a matter of local option. As discussed in the next section, some technologies are not explicitly denied in the coverage issues appendix, even though, according to HCFA staff, the contractors should know that they are not covered. How this knowledge is transmitted is unclear. Furthermore, when contractors encounter claims for technologies that are not included in the coverage issues appendix and which raise issues of national importance because they are experimental or potentially costly, the contractors are expected to ask HCFA for a national coverage determination. However, the criteria for identifying such technologies are not well specified.

treatment of a herniated disc. In both instances, coverage is generally contingent on FDA approval. The timing of the streptokinase is important: respondents require that it be administered from 4 to 6 hours after onset of symptoms; one respondent required that the patient be placed in a specialized care unit postoperatively. In approving chemonucleolysis claims, two respondents require that its use be limited to the lumbar region; two others require that the provider have special training,

Technologies Not Covered by HCFA

For some technologies, HCFA's Office of Coverage Policy expects that claims will be denied, even though there is no HCFA policy explicitly denying coverage. For example, some sections of the coverage issues appendix state that technologies will be covered only in specified circumstances, meaning by implication, that all other uses of the technology will not be covered. The use of biofeedback for intractable pain is the only study technology to fall into this category. Section 35-27 of the coverage issues appendix states:

> Biofeedback therapy is covered under Medicare *only* when it is reasonable and necessary for the individual patient for muscle reeducation of specific muscle groups or for treating pathologic muscle abnormalities of spasticity. . .(etc.). . . This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.

Fifty-five percent of the contractors follow HCFA's intent and reported that they would not cover biofeedback therapy for intractable pain, Reasons given for approving coverage with qualifications include: documentation that all other methods have failed, when used in conjunction with physical therapy, when part of a pain rehabilitation center program, and when used for specific muscle reeducation. (The final qualification listed may indicate that the respondent misunderstood the question. Although specific muscle reeducation would be a reimbursable use of biofeedback, that is not what the question addressed.)

The questionnaire included two other technologies which are not explicitly denied coverage, but for which HCFA believes the contractors should understand that coverage should be denied. In both instances, other uses of the same technology are specifically covered. According to HCFA, percutaneous transluminal coronary angioplasty (PTCA) to eliminate obstruction in two or more coronary arteries should not be covered, even though a single vessel procedure is covered. Almost 52 percent of the respondents would not approve a claim for PTCA involving two or more arteries, while about 38 percent would approve the claim, either with or without qualifications. The reported qualifications suggest that the contractor would review each case individually to determine medical necessity, that the criteria specified for a single-vessel procedure would be applied, that the claim would be approved only if the requested charges were reasonable, and that the claim would be approved, but the level of reimbursement would be the same as for a single-vessel procedure. Presumably, the HCFA restriction on multiple-vessel procedures was based on a concern for increased patient risk; however, it does provide an opportunity for "creative" billing.

The other instance in which coverage should be understood to be denied is the use of apheresis (therapeutic apheresis) or plasma exchange in the treatment of systemic lupus erythymatosis (SLE). Therapeutic apheresis is covered for several indications listed in the coverage issues appendix, but not for systemic lupus. In May 1983, PHS tentatively recommended that apheresis for SLE should not be covered; however, that recommendation was withdrawn and the issue will be reconsidered. This uncertainty is reflected in our responses. Sixty percent of the contractors do not cover apheresis for patients with SLE, while 18 percent would cover without restriction, and another 14 percent would cover with qualifications.

The final category of technologies includes those for which HCFA policy explicitly denies coverage. The highest adherence to that policy is seen in claims for chelation therapy with EDTA in the treatment of atherosclerosis and for topical oxygen therapy (e. g., using a Topox device) in the treatment of decubitus ulcers. The lower rate of claims denial for a pacemaker device for a patient with sinus bradycardia without symptoms may reflect the policy of at least some contractors to submit all pacemaker claims to indepth medical review, prior to making coverage determinations. The primary reason for covering electroencephalographic (EEG) monitoring during open-heart surgery was documentation by a physician that it was needed. Some contractors noted the difficulty of determining whether a monitor was used, indicating that they do not usually receive a separate bill for this, but that the bill for the surgery may be somewhat inflated.

The responses for continuous 24-hour monitoring of blood pressure reflect, in part, changing HCFA policy. Use of a semiautomatic or patient-activated portable monitor had been specifically not covered since October 1982. However, there was no explicit policy regarding coverage of the automatic, continuous monitoring device until July 1983, when coverage was explicitly denied. Some respondents may not have been aware of this recent policy issuance. Furthermore, some respondents appear to have confused the automatic device in the question (which includes a sensing

apparatus and provides continuous monitoring and recording) with an automatic blood pressure monitor that can be covered, if prescribed by a physician for use as part of a home dialysis delivery system. Reimbursement for the latter is limited to the amount which would be payable for a sphygmomanometer with cuff and stethoscope unless there is documentation that the patient's condition is such that conventional methods of monitoring are not successful. Both potential sources of confusion may have resulted in a greater tendency to approve coverage of automatic, continuous, 24-hour blood pressure monitors than would **have** been expected.

In summary, it appears that with the exception of intraocular lens implantation, there is variation in coverage decisions made by Medicare contractors, regardless of HCFA policy. Interpretation of the variation is complicated by the dependence of coverage policy on consensus within the medical community that a given technology is safe and effective. If that consensus is lacking or just emerging, it might be expected that a coverage policy, if one existed, would be lacking in specificity and inconsistently adhered to by contractors. Nevertheless, differences in coverage decisions by Medicare contractors appear to be related to the clarity or specificity of HCFA policy. The variation is least in some instances in which HCFA has explicitly approved coverage. Variation is much greater for technologies that HCFA intends to be denied, but for which there is no explicitly stated denial policy, as well as technologies for which coverage policy is changing. In most instances, however, the majority of contractors adhere to HCFA's intentions.

Contractor's Views and Interpretation of HCFA Coverage Policy

Several questions explored the contractor's perceptions of HCFA coverage policy and the processes by which it is promulgated. For example, the respondents were asked how frequently HCFA coverage transmittals can be implemented as written, rather than requiring further interpretation. As shown in table E-7, over half the respondents indicated that HCFA transmittals can always or almost always be implemented as written. When further clarification is needed, the sources of assistance tend to be the same as those utilized in making any coverage determination (see table E-4).

It was noted earlier that about 88 percent of the respondents indicated that they utilize HCFA's regional office in their area for assistance in making coverage decisions. To ascertain whether there is any predictability in the types of coverage questions referred to the regional office and, perhaps, to HCFA's central office, the contractors were asked whether they used any criteria to determine when to refer a coverage question to HCFA. The responses generally fell into two categories, Some contractors appear to use the regional office rather routinely if the coverage issues appendix does not address the technology in question, HCFA policy is ambiguous, the contractors are not familiar with the technology, or "we don't know what to do. " Other contractors attempt to establish their own policies and use the regional office as a last resort, i.e., only if their own decisions have been challenged by providers or if a technology is experimental and has a potential for abuse. Some contractors are guided by

Table E-7.—Medicare Contractors' Attitudes and Actions Regarding HCFA Coverage Transmittals

	Contractors' response					
	Never	Rarely	Sometimes	Almost always	Always	Number of responses
HCFA coverage transmittals can be implemented as written rather than requiring further interpretation.	7.1 0/0	7.1 0/0	30.40 / 0	35.7%	19.60 / o	56
Contractor informs HCFA regional office of its interpretations of HCFA policy . . .	10.6	25.5	14.9	—	48.9	54
	More	Same	Less	Not applicable		Number of responses
Specificity of HCFA policy compared with policy for other claims reviewed by contractor	35.7%0	26.8%	3.60/o	33.90/0		56

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

the advice of their onsite HCFA representatives about when to refer coverage questions to the regional office.

When contractors take the initiative to further interpret HCFA coverage policies themselves, most of them inform HCFA's regional office of their interpretation (see table E-7). Of those respondents, most have onsite HCFA representatives to whom they automatically send copies of their policy interpretations.

When comparing HCFA coverage policy with policies governing other health insurance claims reviewed by the contractor, most contractors report that HCFA policy is as specific or more specific than policies for other insurance claims (see table E-7). About one-third of the contractors were unable to answer the question, because they review only Medicare claims and had no basis for comparison.

Interrelationships Between Coverage Decisions and Contractor Characteristics

To better understand the extent to which characteristics of Medicare contractors and their claims review processes may influence coverage decisionmaking, several additional analyses were performed. The responses about coverage of individual technologies were categorized according to whether the respondent organization was án intermediary or carrier, whether the contractor was a commercial insurance company or a Blue Cross or Blue Shield plan, and according to the contractor's geographical location, the discipline and position of the individual respondent, claims volume, and the contractor's reasons for and willingness to refer coverage questions to the regional office. Occasionally, statistically significant differences emerged; however, no meaningful trends were observed for any of these analyses.

Contractors' Suggestions for Improving Coverage Transmittals

Given the importance of HCFA transmittals in shaping coverage decisions, the respondents were asked to suggest specific changes that might improve either the process by which HCFA coverage policies are transmitted to Medicare contractors or the content of those coverage policies. The timing of HCFA coverage transmittals is the primary concern of respondents. A majority of them cite difficulties in implementing transmittals simply because they lack adequate lead time to prepare their organizations; some transmittals arrive after the date on which they were to become effective. Suggested improvements include increasing reliance on interim memos and guidelines transmitted prior to the final directive, as well as simply lengthening the lead time for implementation and eliminating retroactive policies.

Many contractors note a need for greater national consistency in interpreting coverage policies. They mention differences in policy interpretations among HCFA regional offices, which may increase contractors' vulnerability to litigation and are particularly troublesome for large commercial insurance companies that serve as carriers in several States. They also note instances in which a single contractor receives a policy determination from HCFA's central office in response to an inquiry; that is not shared nationwide, the result being inconsistent interpretation of coverage policy. These problems, as well as inadequate local resources for contractors to pursue the status of new technologies themselves, lead many contractors to recommend the creation of a national coverage clearinghouse. Such a clearinghouse, perhaps supported by the Government, insurance companies, and medical and specialty associations, could disseminate information on new technologies, the status of their evaluation, and implications for coverage policies. It should also be noted, however, that many contractors are quite content with the status quo and prefer to utilize local resources in making their own coverage decisions.

Another area of concern is the specificity of HCFA coverage transmittals. Contractors report that the policies are too technical, too ambiguous, and lacking in specificity. The need for more specific criteria for covering durable medical equipment was frequently mentioned, as well as the need to update all references to a specific technology in order to eliminate inconsistencies within the coverage issues appendix and manual. Several respondents note that the content of coverage transmittals is improving, citing the policy covering pacemakers as a good example. On the other hand, one respondent cited the pacemaker issuance as indicative of the failure of HCFA's central office to understand the claims review process. In this respondent's opinion, the policy governing pacemakers does not take into consideration the process by which claims are submitted and the information included on the claim, making it impossible to process the claim without extensive and expensive investigation. Some contractors thought that these issues were not worth debating, because Medicare's move to prospective payment will render any changes outdated or useless. Still others felt the coverage issues appendix is clear and sufficient and that the coverage system as a whole works "remarkably well. "

Summary and Conclusions

This study has confirmed the conventional wisdom that there is variation in the decisions made by Medi-

care contractors regarding the coverage of particular medical technologies. There are high levels of agreement and near unanimity in coverage decisions for some study technologies—particularly for intraocular lens implant following cataract removal (98.2 percent covered), the use of chelation therapy in the treatment of atherosclerosis (87.0 not covered), and the use of topical oxygen therapy for decubitus ulcers (86.3 percent not covered). However, there are also examples of wide variations in coverage policies—particularly for a pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms, an implantable chemotherapy infusion device for a patient with metastatic to the liver cancer, and external insulin infusion pump for a diabetic patient, and streptokinase administration at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction.

Despite these variations in coverage policies, there is considerable uniformity among contractors in the methods by which claims are reviewed and national coverage decisions are implemented. After an initial review for completeness, most claims pass through (potentially) three levels of review that reflect differing degrees of comprehensiveness, specificity, and clinical judgment. The levels of review generally involve clerical employees, registered nurses, physicians, or some other health professionals (pharmacist, podiatrist, occupational therapist, etc.) in that order. Although the specifics may vary, general considerations at each level of review are similar, as are the criteria for referring a claim from one level of review to the next. Eighty-four percent of the respondents use some type of automated screening procedure. When revisions or additions to the coverage issues appendix are received from HCFA, most contractors review them internally and modify their claims review procedures accordingly. Coverage issues requiring further clarification are pursued either locally or nationally; HCFA's regional offices are the most frequently utilized sources of clarification and interpretation.

Similarly, the methods by which contractors identify new technologies or new uses of established technologies are quite predictable. Most contractors report that they learn about new technologies for which coverage questions might be raised through inquiries from providers and manufacturers prior to the actual submissions of claims, drug and device approval lists from FDA, and HCFA announcements. Once claims are submitted, new technologies are identified because of the absence of code numbers or the presence of codes that are not recognized by the claims reviewers. Although a few contractors conduct extensive research to assist in identifying and making coverage decisions for such claims, the majority assume a more passive role. The majority are reasonably well satisfied with existing methods for identifying new technologies and report that this is not a big problem for them. Making coverage determinations for new technologies is a problem, however.

Some characteristics of the contractors included in the study did vary. The respondents include a mix of intermediaries and carriers; some are commercial insurance companies and others are BC/BS plans; they come from different geographic locations, handle different volumes of claims, and show different tendencies and reasons for referring coverage questions to HCFA's regional office, rather than attempting to resolve the issue themselves. Nevertheless, these characteristics were not systematically related to variations in coverage decisions in any meaningful way.

The most illuminating approach to examining variations in coverage decisions was based on coverage policy, according to the following categories: technologies that HCFA explicitly covers; those that HCFA covers with qualifications; technologies that HCFA explicitly denies; those that HCFA denies, but not explicitly; and those for which HCFA has no explicit policy, but rather, the local contractor is expected to determine coverage policy. There is variation in every category of HCFA coverage policy, with the possible exception of claims for intraocular lens implantation. Interpretation of that variation is complicated by the dependence of coverage policy on consensus within the medical community that a given technology is safe and effective. If that consensus is lacking or just emerging, it might be expected that a coverage policy, if one existed, would be lacking in specificity and inconsistently adhered to by contractors. Nevertheless, the differences in coverage decisions by Medicare contractors appear to be related, at least in part, to the clarity or specificity of HCFA policy. The variation is least in instances in which HCFA has explicitly approved coverage. Variation is much greater for technologies that HCFA intends to be denied, but for which there is no explicitly stated denial policy, as well as technologies for which coverage policy has recently changed or is expected to change. Despite the variation, however, when the responses for individual technologies are analyzed, the preponderance of respondents tend to adhere to HCFA intentions.

If less variation in coverage decisions is desired, the study findings suggest some ways in which this might be accomplished. Greater specificity and uniform interpretation of wording would help to lessen the uncertainty about the technologies that HCFA intends to be denied, but for which denial is not explicitly stated in written policy. Similarly, uniform and more timely

communication from HCFA might lessen the variation in coverage for technologies that are currently being reviewed by PHS or for which policy is expected to change. The respondents' suggestions about a national coverage clearinghouse should also be considered.

Reducing variation in coverage decisionmaking should help to eliminate any existing inequities in the availability y of benefits to persons eligible for Medicare. To the extent that a technology is not intended to be covered, greater adherence to HCFA policy would also save money. If changes in coverage policy are intended to influence the proliferation and use of medical technology so as to result in significant cost savings, however, more major revisions are needed in the way in which coverage determinations are made. The cost effectiveness of technologies would have to assume a more prominent role in coverage deliberations, as well as the possibilit of 1imiting the health care settings and providers who would be eligible to claim reimbursement.

The potential for increased equity of benefits and financial savings that might accrue from more uniform coverage decisions must be balanced against the potential negative effects. It is unlikely that any nationally determined, uniform coverage policy can ever take into consideration the uniquely personalized needs of all patients. In some small number of cases, increased uniformity of coverage probably would occur at the expense of quality of care. Carried to the extreme, increased explicitness of coverage policy may have a negative effect on access to care and the potential for innovation in medicine. Furthermore, the costs of implementing and enforcing a uniform system might outweigh the advantages.

In the final analysis, the decision to reduce variation in coverage policy and increase the explicitness and uniformity of Medicare benefits requires careful judgment and balance. Some lessening in that variation appears to be desirable and achievable, provided it is carefully coordinated with forthcoming changes in the overall reimbursement system. However, it is unlikely that HCFA policy can ever be so precise as to achieve a totally uniform interpretation and implementation of Medicare coverage policy throughout the Nation.