

3.

Payment Policies for Health Care and Medical Devices

We prefer to blame technology rather than our cultural institutions for the great cost overrun of the American health care system

-Dale R. Olseth

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3.

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INTRODUCTION

The market for health care services is more complicated than most other sectors of the economy. The ultimate consumers of health care typically do not pay for services at the time they are rendered; third-party payers—insurance companies, Medicare, Medicaid, and other Government programs—share in the cost of providing medical services to their beneficiaries. Only about 32 percent of total personal health care expenditures are paid directly by patients (128).

The market for health care services is also complicated by the central role of the provider—the physician, other health professional, or hospital—in making decisions about the amount, kind, and quality of services that the patient receives. Most diagnostic and therapeutic medical procedures, prostheses, and implants must be ordered by the physician. Thus, the makers of medical devices more frequently see the provider as the buyer than they do the patient or consumer.¹

Manufacturers of medical devices, like those of other products, try to produce and price products to meet the demands of their market. If low price is important to buyers, then, barring the existence of monopoly power,² the producers will attempt to make products that can sell profitably at low prices. If price is not so important to customers, producers will focus on factors that are. Since the system of third-party payment for health care services influences the products that will be bought and the prices that will be paid, it is a major determinant of the market for medical devices.

Payment issues also influence the long-run performance of the industry. In general, the success

¹An important and growing class of devices are those made expressly for use in the home or by the consumer. These include self-care products such as self-testing diagnostic kits and aids for handicapped people that are often marketed directly to the consumer.

²This assumption is important in gauging the response of the industry to the preferences of consumers.

or failure of a technological innovation rests partly on developers' perceptions of its market (201,232,264). Although technological opportunities may dictate what directions of advance are feasible, the perceived existence of a market for an innovation is necessary for the commitment of research and development (R&D) funds or the investment in commercialization. There is no evidence to suggest that the medical device industry is different from other industries in this regard.

Other factors besides the payment system shape markets for medical devices. Both the benefits and costs of medical devices matter. First, the buyers and users must perceive a device to be worthwhile. Devices that are unsafe, ineffective, or less effective than their substitutes may not have a market even in the presence of generous third-party payment. Gastric freezing is an example of a device-bound procedure that was abandoned soon after evidence accumulated that it did not help ulcer victims, in spite of the willingness of third-party payers to finance its use (114). However, many devices have been widely used even though well-documented evidence of their effectiveness is lacking.

Second, the availability of an important new device whose cost, configuration, or setting of use currently limits or proscribes third-party payment (an stimulate a change in payment policy. The case of long-term hemodialysis therapy for end-stage renal disease is a classic example (256). With the development of a subcutaneous arteriovenous shunt (a plastic tube connected to an artery and a vein in the arm or leg) by Quinton and Scribner In 1960, hemodialysis rapidly became accepted as a life-extending therapy for victims of chronic kidney failure.

In 1972, Congress extended Medicare coverage for treatment of end-stage renal disease to the gen-



Photo credit: National Kidney Foundation, Washington, DC

This man is undergoing hemodialysis for the treatment of end-stage renal disease (ESRD). Medicare began paying for such treatment in 1973, and by 1982, expenditures for Medicare's ESRD program were an estimated \$1.8 billion.

era] population (Public Law 92-603), largely out of a recognition that there occurred an estimated 7,000 to 10,000 deaths per year because of the limited availability of dialysis facilities (256). This program now pays \$1.8 billion annually for hemodialysis for approximately 80,000 people (98).

Third, many new medical devices are perceived to have such benefit that they are demanded whether or not they are covered by insurers. In dentistry, for example, many new materials have been developed in the recent past (184,210), despite the fact that almost 70 percent of dental expenditures are paid directly by patients (128).

With the recognition that other factors affect the markets for medical devices, this chapter describes how third-party payment, particularly Federal payment programs, affects the kinds of

medical devices that are produced, the settings in which they are used, and the prices at which they sell.

Medicare and Medicaid, the two Government health insurance programs, are responsible for about 35 percent of payments for personal health care made to hospitals, 23 percent of those to physicians, and 23 percent of all other medical expenditures (128). Private health insurance, including commercial (for-profit) insurance companies and (not-for-profit) Blue Cross/Blue Shield plans, accounts for another 33 percent of hospital and 35 percent of physician expenditures. Other Federal, State, and local government programs also contribute 13 percent of personal health expenditures through the Veterans Administration (VA), the military medical system and its related Civil-

ian Health and Medical Program of the Uniformed Services (CHAMPUS) program, and Government owned and operated health facilities (128).

If all sources of third-party payment and Government funding are taken together, the individual consumer or patient bears a moderate proportion of the burden of personal health care expenditures in this country (32 percent). But the distribution varies widely by settings and types of technology. Patients pay only about 12 percent of hospital expenditures directly, but they pay 37 percent of payments to physicians and almost 77 percent of expenditures for eyeglasses and appliances (128). The burden of payment also varies widely in the population. Some people have comprehensive health insurance, although an estimated 32.7 million people under age 65—or about 16 percent of the population under age 65—were without any public or private insurance coverage in 1982 (295a).³

³The uncovered population increased dramatically between 1979 and 1982. In 1979, 14.4 percent of those under 65 years of age were uncovered, and in 1982, 18.9 percent of those under 65 were un-

Three aspects of third-party payment can influence the potential market for medical devices:

- the coverage of devices as benefits by third-party payers;
- the methods used to determine the level of payment for covered health services; and
- the financial relationship between the payer and the provider of health care.

Each of these elements is discussed in the sections below.

1979 covered. Economic conditions in the period and increases in the costs of health insurance relative to other goods and services are responsible for these changes (295,296).

THIRD-PARTY COVERAGE OF MEDICAL DEVICES

Economic theory predicts and empirical evidence confirms that the existence of insurance coverage for a technology increases the number of such services used (29,233,279). It has also been shown that the use of physician and hospital services varies inversely with the amount of cost-sharing required of the consumer (233). Not only have people sought care less often under cost-sharing, but their total annual health expenditures have been lower than for people without cost-sharing requirements. Insurance coverage also affects the adoption of new medical technologies. In two studies, a positive relationship was found between the proportion of a State's population with health insurance and the adoption of complex and sophisticated facilities in hospitals (71,266).

Most health insurance plans are selective in their definition of covered technologies. Insurers avoid certain services whose use may be difficult to predict or control. For example, mental health services are frequently excluded from both pub-

lic and private insurance policies, as are some long-term care and home health services (55). The Medicare program covers inpatient hospital care more fully than other services but requires some cost-sharing by beneficiaries and limits the number of hospital days covered.⁴ Physician services and ambulatory laboratory services are covered, but annual deductibles and copayments are required of beneficiaries. Other services, such as outpatient drugs, eyeglasses, hearing aids, and preventive services are either uncovered or covered to a very limited extent under Medicare (345).

Coverage decisions are often more complicated than the all-or-nothing decision about general classes of services. By statute, Medicare may pay

⁴Medicare consists of two separate but coordinated programs—Hospital Insurance (Part A), and Supplementary Medical Insurance (Part B). Under Part A, beneficiaries receive up to 60 full days of hospital care per year after a deductible is satisfied. Part B, which is voluntary and requires a premium, has both a deductible and a beneficiary payment of 20-percent coinsurance.

only for services that are "reasonable and necessary" for diagnosis, treatment, or improved functioning of a malformed body member. Medicare has refrained from establishing a definitive interpretation of reasonable and necessary and has relied on a loosely structured and decentralized mechanism to determine whether a specific service is covered. Under the present Medicare program, funds are passed from the Federal Government to many separate contractors (referred to as intermediaries and carriers) who reimburse providers or consumers for the services delivered in their areas.

The contractors are responsible for implementing Medicare coverage policy. Decisions involving coverage of services, particularly new services, are often made on a case-by-case basis and thus may vary from region to region. For example, prosthetic devices may be covered under Medicare if they replace all or part of an internal body organ or replace the functioning of a permanently inoperative or malfunctioning organ. But communications aids, considered by numerous health professionals to be prosthetic devices, are not specifically covered under Medicare. Coverage is largely at the discretion of the contractor (345).

A rather informal system exists for referral of coverage issues that cannot be resolved by the contractor to Medicare's regional office and, if necessary, to the Federal Health Care Financing Administration (HCFA), which often turns to the Office of Health Technology Assessment¹ in the Public Health Service for guidance. There is apparently some chance involved in which issues get flagged for referral (343).

Medicare contractors vary widely in their identification of uncovered technologies, the decisions

¹Coverage is important for new devices where payments are made for each service delivered as in a fee-for-service system. In Medicare, coverage affects the services of physicians and other health professionals more than hospitals, because they are paid on a fee-for-service basis whereas hospitals are paid by the admission.

²The Office of Health Technology Assessment (OHTA) in the Department of Health and Human Services is the office in the Public Health Service that is charged with advising HCFA on Medicare coverage of specific technologies. OHTA is distinct from the Office of Technology Assessment (OTA), a staff agency of Congress that performs studies requested by congressional committees and has a Health Program.

they make concerning the coverage of specific technologies, and their implementation of coverage decisions (51,79,343). In short, coverage of some services, particularly new procedures, under Medicare is variable and uncertain. Such uncertainty may reduce in the eyes of the developer the expected monetary return from introducing a new medical device whose coverage is questionable. Increasingly, the manufacturers of new devices have themselves approached HCFA for definitive guidance on coverage (345), perhaps in an attempt to reduce the interregional variation and uncertainty associated with the coverage process.

In general, third-party payers will not cover a new device until it is approved for marketing by the Food and Drug Administration (FDA) (see ch. 5). For example, Medicare will cover no drug or device that is in the investigational category. It is interesting to note, however, that the Medical Device Amendments of 1976 (Public Law 94-295) do not prohibit the manufacturers of an investigational device from selling their product to users. The producer may charge a price for an investigational device that will recoup research, development, and production costs but may not make a profit.

Although the buyers (health care providers) generally cannot charge third-party payers directly for an investigational device, they can sometimes charge for it through other, similar, procedures that are already covered.² In the words of one legal expert, "investigational devices pay their own way" (84). This expert also noted that large and small device-makers charge institutions, practitioners, and patients for devices that are available only under an FDA investigational device exemption (IDE).

Some investigational devices have become widely diffused in the absence of either premarket approval or specific coverage by the major third-party payers. As an example of FDA's policy of limiting distribution of devices under IDE, the agency recently issued a "guidance" letter to nine manufacturers of yttrium aluminum garnet (YAG) lasers (used in ophthalmology) limiting investigational uses to 500 patients in a 6-month period

²If the device is part of a research program, a research grant may pay for its use.

because it was concerned that the widespread distribution of these devices still in the investigation stage constituted commercialization (88).

Limitations on and exclusions from coverage increase the difference between the out-of-pocket price of covered and uncovered services. When covered and uncovered services compete as substitutes for one another, the uncovered services are at a distinct disadvantage. To have a chance of being used, the uncovered service would have to offer patient benefits sufficiently greater to justify the higher out-of-pocket expense. The effect of differential coverage levels on the market for a medical device depends, of course, on whether the device is covered by most insurance plans, which patient conditions are covered for payment, whether substitutes for the device exist—and if substitutes exist, whether these alternative services are covered under insurance policies as well.

The effects of a coverage decision on medical devices vary with the specific characteristics and conditions of use of devices. For example, a new cataract removal procedure made possible by a new device may lower the cost to the physician of performing the procedure. The physician can introduce the cost-saving method and bill the patient or insurer for the standard cataract removal procedure (at fees that are not likely to reflect the reduced costs).⁸ Thus, to the extent that new techniques or devices can be subsumed under existing medical procedure categories, coverage is not of great concern. However, if the cost of the new approach is higher than the level of payment for existing procedures, coverage becomes an impor-

⁸See the section below on “Payment for Physicians devices” for an explanation of this phenomenon.

tant milestone in the development of a viable market for the technique. Using old procedure codes for the new technique will not be attractive to physicians.

Although the introduction of some new medical devices may be discouraged by the practical obstacles to third-party coverage, there is no ongoing mechanism in Medicare to reverse coverage decisions when an existing device has been found to be less effective than other approaches. For example, Medicare has continued to cover intermittent positive pressure breathing (IPPB), a mechanical ventilator for respiratory therapy (246,272), despite the fact that several professional societies have seriously questioned its value.

The history of IPPB also illustrates the important role of professional judgment in influencing the use of a procedure. Despite the coverage by third parties, the use of IPPB has decreased dramatically in the past decade (see box C) (20,43, 49,248,272).

Thus, it appears that the process by which devices come to be covered (or removed from coverage) by third-party payers is idiosyncratic. Under Medicare, some devices are “grandfathered” into coverage by virtue of their age; some are covered by default because they can be paid within preexisting medical procedure codes. Others are denied coverage, or given very limited coverage for a period of time. The degree of ease with which a particular device receives the blessing of coverage from the major third-party payers appears to have little to do with the device’s relative efficacy or cost effectiveness (24) and more to do with the accident of timing of its introduction to medical practice.

METHODS OF THIRD-PARTY PAYMENT AND THE DEMAND FOR MEDICAL DEVICES

Insurers use a variety of mechanisms to pay for covered services provided to their beneficiaries. In the simplest case, the insurer makes fixed indemnity payments to the beneficiary, who is responsible for paying the provider whatever is charged. Other plans pay for the full costs of serv-

ices to the beneficiary (less any deductibles and coinsurance) up to a schedule of maximum allowances.

Medicare, Medicaid, and many Blue Cross/Blue Shield plans enter into contracts with “par-

Box C.-Intermittent Positive Pressure Breathing (IPPB)

IPPB devices are mechanical ventilators which, once triggered by the beginning of the patient's inspiration, deliver a single "breath" of air. Such devices can be adjusted for sensitivity so that even very weak patients can trigger the machine with every attempted breath. The patient usually uses only a mouthpiece, although a face mask can also be used (467).

The four basic functions of IPPB devices are: 1) to inflate the lungs fully; 2) to deliver any specified mixture of **gases** (including room air) to the lungs; 3) to deliver aerosols (either bland, to moisten the lung, or medicinal); and 4) to stabilize breathing. Common alternative respiratory therapy devices include blow bottles and incentive spirometers, which help inflate the lungs, and nebulizers, which deliver aerosols. IMS data show that sales of IPPB devices have decreased by about one-third in the past 5 years, while sales of nebulizers, for example, have doubled in the same period (166). Professional-journal articles have also reported that use of IPPB devices has decreased since the early 1970s (20,43,248,272).

Reasons for the decrease in IPPB sales and use are not related to payment policies. Rather, the medical profession began in the early 1970s to scrutinize criteria for respiratory therapy in general and the administration of IPPB therapy in particular (266,287).

IPPB emerged out of World War II efforts to provide adequate ventilation for high-altitude pilots. A landmark paper by Motley and his colleagues in 1947 (221) introduced the clinical use of IPPB to the medical profession. The 1950s and 1960s saw the gradual diffusion of IPPB technology into hospitals and homes (58,459). Criticisms of indiscriminate use were published, but use increased dramatically nonetheless (25).

With the adoption of Medicare and Medicaid legislation in 1965, the public endorsed IPPB use. No conscious decision to cover this procedure was ever made; the technology was in widespread use at the time of passage. Blue Cross/Blue Shield plans also covered treatments without question,

IPPB therapy was common long before any rigorous tests of its efficacy were made. The clinical studies reported in the literature during its diffusion tended to use methods that were poorly designed or difficult to duplicate (272). The lack of good clinical data exacerbated the controversy over its proper use.

In the 1970s, several professional groups began to strongly question the use of IPPB devices. A 1974 National Heart and Lung Institute conference on the scientific basis of respiratory therapy concluded that the literature on IPPB warranted closer examination of the technology, especially through controlled clinical trials. By the time of the National Heart, Lung, and Blood Institute (NHLBI) conference in 1979, respiratory therapy textbooks were beginning to emphasize more stringent criteria for IPPB use (467), and the American Association of Respiratory Therapists (AART) had endorsed guidelines for we prepared by the American Thoracic Society (4).

Shortly after the 1979 conference, an OTA-contracted case study circulated a critical appraisal of IPPB to a slightly different audience (272). With this report to give it credibility, the Blue Cross/Blue Shield Association began an assessment of IPPB use and insurance coverage, in cooperation with the American College of Physicians and other professional groups (36).

While public awareness of the potential for IPPB overuse has risen, the controversy in the medical profession has slowed considerably. "Consensus papers" such as the AART and Blue Cross Shield guidelines still may find strong opposition on some points (278), but there has been little hard argument carried in medical journals in the past few years. A 1981 NHLBI Task Force on Pulmonary Technology did not even mention IPPB (402).

ticipating” providers that specify the methods for determining the level of payment that providers will receive. Because of the importance of Medicare, Medicaid, and the Blue Cross/Blue Shield plans as sources of revenue, these methods of payment are critical determinants of the market for medical devices.

Methods of payment vary widely across insurers and settings of care. This section will focus on current and proposed methods of paying for inpatient hospital care, physicians’ services, laboratory tests provided in ambulatory care settings, and services or devices used in the home. These four components constitute over 80 percent of health expenditures and make intensive use of medical devices.

Hospital Payment

Public and private third-party payers were responsible in 1980 for over 83 percent of the revenues of community hospitals in the United States (108). Private health insurance itself accounts for 38 percent, while Medicare and Medicaid comprise 42 percent. Individual patients are the source of about 17 percent of the revenues of community hospitals.

Third-party payment for hospital care has traditionally taken two forms: payment of billed charges and payment of incurred costs. Most commercial insurance plans and about one-third of the 70 Blue Cross plans pay hospitals their billed charges.¹ In 1981, over one-half of the State Medicaid programs and about one-half of the Blue Cross plans reimbursed hospitals for the “reasonable costs” incurred in serving their beneficiaries (6,345). Medicare is in the process of abandoning this method of payment and moving to a new system, discussed later in this chapter. Both of these payment methods (by charges and costs) pass the immediate burden of payment through the patient to the third-party payer.

Charge- and cost-based third-party payments encourage increases in health care expenditures, because hospitals have no incentive to hold costs

¹A small percentage of commercial policies are indemnity plans, where the insurer pays the patient a fixed amount, such as \$100 per day of hospitalization. Only about 10 percent of group policies written by commercial insurance companies are indemnity plans (456).

down.” Only to the extent that patients themselves react to costs (or charges) by taking their business elsewhere (if they can) will the hospital have an incentive to compete for patients in terms of price. Since patients themselves pay so little out-of-pocket for inpatient care, they have little incentive to concern themselves with price. The predominance of third-party cost- and charge-based payment has been held responsible for the rapid increase in hospital expenditures (110).

The problem of growing hospital expenditure inflation increased during the 1970s and led both public and private third-party payers to modify payment methods. A number of Blue Cross plans, individual States, and now the Federal Government have turned to prospective payment.¹¹ Although prospective payment methods vary widely among States and payers, they have two features in common: the amount that a hospital is paid for services is set prior to the delivery of those services, and the hospital is at least partially at risk for losses or stands to gain from surpluses that accrue during the payment period.

Evidence has accumulated that in recent years some State-level prospective payment programs, particularly those with relatively stringent systems, have had a moderating influence on hospital costs (33,60). What have these reductions in hospital costs implied for the adoption of medical technology? Three studies of the impact of hospital prospective payment programs on the adoption of new capital equipment or equipment-embodied services suggest that prospective payment sometimes does affect technology adoption and that the directions of effect depend on both the specific attributes of the programs and the characteristics of the new technology.

Joskow found that the number of computed tomography (CT) scanners located in hospitals in a State in 1980 was negatively related to the number of years that ratesetting had been in effect there (177). Hospital ratesetting also led to a shift in the location of CT scanners to physicians’ of-

¹¹Such incentives apply when costs of production are reimbursed, as under Medicare, but differ when payments are below costs as under some Medicaid programs (138).

¹²Prospective payment has also been called prospective reimbursement

fices. Cromwell and Kanak analyzed the impact of specific State ratesetting programs on the availability of 13 different services in the hospital between 1969 and 1978 (72). Two States with stringent programs, New York and New Jersey, had the most consistently negative effects on the availability of services. Other States' programs showed no consistent impact on service adoption.

Finally, Wagner and colleagues investigated the impact of prospective payment in three States—New York, Maryland, and Indiana—on the adoption of five new pieces of capital equipment: electronic fetal monitoring, gastroendoscopy, volumetric infusion pumps, automated bacterial susceptibility testing, and computerized energy management systems (448). The first three technologies are likely to raise the cost of care, while the latter two are investments in equipment that is cost-reducing in large hospitals. Under New York State's ratesetting program, fewer units of the cost-raising technologies were adopted, and the probability of large hospitals' adopting the cost-saving equipment increased. However, the prospective payment programs in Maryland and Indiana showed no such consistent effects on hospitals' adoption behavior.

Medicare's DRG Hospital Payment System

In March 1983, Congress established a new Medicare hospital prospective payment system (Public Law 98-21). Beginning in October 1983, Medicare began to phase in a system in which it will pay hospitals a fixed price for treating each admission in 470 separate diagnosis related groups (DRGs) of patients. At this time, the price paid for each admission in a particular DRG covers hospital inpatient operating costs—leaving outpatient, teaching, and capital expenses reimbursed on a cost basis for the time being.

The new system is a Medicare-only approach, but the law allows Medicare to join State-run prospective plans to cover all kinds of payers. Support from private insurance companies and businesses for these systems is high. Thus, the Federal move into prospective payment may presage a more general adoption of this kind of payment by States.

Because Medicare accounts for such a large percentage of hospital revenues, the new per-case payment system should put into place strong incentives for hospitals to change their behavior regarding the adoption and use of medical devices, as well as all other inputs, because hospitals will be able to retain any surplus and must bear all deficits. One can expect the adoption of some devices, particularly those that reduce the cost per hospital stay, to be encouraged, relative to their past experience. Compared to practice in the recent past, the adoption of cost-raising devices will be discouraged, but the strength of that effect will depend on the device. Some maybe less affected if hospitals compete for admissions by adopting new device-embodied services, while others that do not affect the competitive position of hospitals are likely to face a more hostile adoption environment (see box D for more detail).

The new Medicare payment system should also alter the settings in which services are delivered to Medicare patients. In particular, the use of nursing homes and home health care should increase as hospitals seek to reduce the lengths of stay of Medicare patients. Moreover, payment for care delivered in these settings is not so constrained as that in the hospital. Devices that can be used in the home should find an increasing market.

Some observers are predicting, for example, that the already growing market for parenteral and enteral nutrition (techniques of direct feeding into the bloodstream or gut) in the home will be increased by DRG payment, and that hospitals will enter the market as providers of after-hospital home care in direct competition with other providers, some of whom are manufacturers of equipment and supplies for parenteral and enteral nutrition (34).

The law may also influence the pricing behavior of device manufacturers. As hospitals become more price-conscious with the advent of per-case payment, they are likely to increase their use of group purchasing, standardization of purchasing, and competitive bidding for equipment and supplies. Group purchasing as a phenomenon has grown rapidly among hospitals in the United States, with an estimated 88 percent of hospitals belonging to a purchasing group in 1981 (99), but

Box D.—DRG Hospital Payment: Predicted Effects on Selected Medical Devices¹

<i>Product category</i>	<i>Typical products</i>	<i>Predicted effects</i>
Implants	Pacemakers, heart valves, artificial joints, orthopedic plants, intraocular lenses	For those high-cost implants that represent a large fraction of the DRG rate, increased focus on product selection, with unit cost important.
Chemical laboratory equipment and supplies	Clinical chemistry, hematology and radioimmunoassay instruments; microbiology systems	Increased hospital demand for cost-reducing, highly productive laboratory instruments. Downward price pressures and efforts to control inventories in laboratory supplies. New tests leading to early diagnosis and shorter stays accepted readily. Shift of some testing (e.g., preadmission) outside hospitals.
Patient monitoring equipment	Intensive care unit (ICU) monitoring systems, electronic fetal monitors, blood gas monitors, monitoring electrodes and supplies	Hospital under heavy pressures to limit access to monitoring services wherever benefit is questionable. Hardware innovations carefully evaluated for utility and cost effectiveness. Demand for longer lasting, labor-saving, more reliable new products. Market may shift to larger hospitals.
Respiratory therapy products	Breathing circuits, intermittent positive pressure breathing (IPPB) apparatus, nebulizers, ventilators, oxygen delivery systems, associated supplies	Use of these products may be reduced whenever there is no clear-cut and obvious need. Careful scrutiny of all replacement decisions; less interest in marginal improvements.
Diagnostic imaging and therapy systems	X-ray, ultrasound, computed tomography, nuclear imaging, angiography, film, cassettes, supplies	Demand will remain high because of measured utility and relatively noninvasive nature. Price competition in supplies likely to increase and overall market for supplies will shrink as utilization is curtailed.
Bedside services and disposables	Disposable bedpans, wash-basins, toiletries	Two opposing incentives: increased admissions will increase demand; pressure to reduce cost leads to more careful hospital purchasing and closer evaluation of routine distribution of these products.

¹Based on the Health Industry Manufacturers Association's Prospective Payment Fact Book as discussed in *Medical Device and Diagnostic Industry*, "The Effect of DRGs on Devices and Diagnostics," vol. 6, No. 2, pp. 31-36, February 1984 (211).

it is still largely confined to drugs and hospital supplies as opposed to equipment.

There is some evidence that the VA has been able to exact significant price concessions from manufacturers through its competitive contract purchasing system (see ch. 7). A recent survey of 25 hospitals in 10 States by the Inspector General of the Department of Health and Human Services (DHHS) found that the price of cardiac

pacemakers for Medicare patients was about 17 percent higher than the price paid by the VA
1271

As hospitals face increasing pressure to reduce the costs per admission under the new payment system standardization of purchasing behavior is likely to occur, reducing the range of choice open physicians and allowing hospitals to reap benefits of increased market power. The ex-

pected result in any particular device category is narrower price ranges and less variation among products.

An unresolved issue with important implications for medical devices is how Medicare will pay for hospitals' investments in capital plant and equipment in the future. For the present, the method of payment for capital costs (depreciation, interest, and return-on-equity to for-profit institutions) has not been changed. Capital expenditures 'are reimbursed as they are incurred, on a cost basis. Congress has expressed an intention to include payment for capital by 1986 as part of the prospective payment rate, but no specific method has been selected.

The present cost-based method of capital payment is inefficient because hospitals have little incentive to weigh the costs and benefits of purchases and hence are likely to adopt and use medical equipment regardless of the cost effectiveness. Table 19 indicates how hospitals' incentives to adopt different kinds of capital equipment under DRG payment are influenced by a passthrough of capital (payment of the capital costs that are incurred).

The capital payment method does not reverse incentives of DRG payment so long as the effect on total hospital costs of a medical equipment purchase is in the same direction as its effect on operating costs. For example, DRG payment provides a disincentive to adopt most cost-raising, quality-enhancing (Type I) capital equipment. Regardless of the way capital costs are handled, such purchase would raise operating costs. The capital

passthrough weakens the disincentive to adopt this kind of technology, but it does not remove it. Since DRG payment sets up incentives for hospitals to increase admissions, they have a financial interest to seek cost-raising equipment whose availability promises to bring in profitable admissions by attracting physicians and patients. A capital cost passthrough essentially subsidizes this kind of investment, leading potentially to wasteful duplication of these services among hospitals.

With equipment that saves operating costs (Type II) or capital costs (Type III), there can be situations where the policy regarding payment for capital may actually reverse the incentives of DRG payment regarding adoption. Of particular concern is the incentive under a capital passthrough to adopt expensive capital equipment that reduces operating costs but raises total cost per case. For example, with a capital passthrough, automated laboratory equipment might be evaluated in terms of its ability to reduce operating costs, with inadequate regard for its impact on total costs. And a more labor-saving capital-intensive system might be preferred regardless of its impact on net costs.

New, inexpensive equipment that replaces older, more costly equipment but only at the expense of increasing operating costs (Type III) will also be discouraged in a DRG system with a capital cost passthrough even if its adoption would decrease total costs (Type III-B). Over time, then, hospitals can be expected to become more capital-intensive than efficiency would dictate if the capital passthrough is continued.

Table 19.—Impact of Medical Equipment on Per-Case Hospital Costs

Type of equipment	Direction of effect of equipment purchase on:			Incentives for adoption	
	Capital cost per case	Operating cost per case	Total cost per case	With capital in DRG rate	Without capital in DRG rate
I. Cost-raising, quality-enhancing equipment	+	+	+	-	
II. Operating cost-saving equipment					
A. Raises total costs	+		+		+
B. Saves total costs	+			+	+
III. Capital cost-saving equipment					
A. Raises total costs	-	+	+	-	
B. Saves total costs	-	+	-	+	-

SOURCE: Office of Technology Assessment

Payment for Physicians' Services

As the primary gatekeeper for the use of medical procedures, the physician is a key actor in decisions bearing on the adoption and use of medical devices. Most diagnostic and therapeutic services must be ordered by a physician or provided under a physician's direction. Although the patient always has the right to refuse services and can refrain from seeking care in the first place, this course is restricted by consumers' limited knowledge and a medical care system that exhorts that patient to "follow doctor's orders." The key role of the physician is reinforced by extensive insurance coverage, which reduces the patient's economic incentive to refuse or question services (139).

In 1982, physicians received approximately 37 percent of their revenues directly from patients, 35 percent from private insurance, 18 percent from Medicare, almost 5 percent from Medicaid, and the remainder from private philanthropy and other sources of Government support (128).

Third-party payers generally pay for covered physicians' services on a fee-for-service basis. There are two primary approaches to determining levels of payment: the benefit schedule and the fee screen (285). Under the benefit schedule approach, the insurer pays the patient or physician a predetermined fixed amount for each covered service. In private insurance plans, the patient is responsible for paying the difference between the physician's fee and the amount of the benefit, as well as any deductibles and coinsurance.

The fee-screen approach, used by Blue Shield plans, Medicare, and some Medicaid programs and commercial major medical plans, pays the physician's actual charge (less coinsurance and deductibles) up to some maximum amount that is computed from profiles of the physician's own fees and those of other physicians in the same specialty and region. This fee-screen approach is generally referred to as the usual, customary, and reasonable (UCR) approach to payment. Medicare uses a variant of the UCR system called customary, prevailing, and reasonable (CPR). Here, the CPR will refer to the general system of computing

a payment rate based on historical and comparative profiles of physicians' fees.

Under its CPR system, Medicare pays 80 percent of the "reasonable charge": the lowest of the actual charge, the customary charge, or the prevailing charge for a service. The customary charge is the median charge for that service by the doctor, and the prevailing charge is the charge below which lies 75 percent of all charges for that service by doctors in a particular specialty and geographic area. Unless the physician enters into an agreement with the insurer to accept the CPR amount as payment in full (i.e., accepts assignment), which occurs in about 50 percent of all claims (113), the patient is responsible for paying the difference between the UCR rate and the physician's billed charge.

Beginning in 1976, increases in the Medicare prevailing charge have been restricted to a rate reflecting increases in personal income in the United States and the costs of medical practice. Over time, as physicians' actual fees meet or exceed the prevailing charge, Medicare's CPR system is becoming a de facto geographic- and specialty-specific benefit schedule. Thus, the difference between benefit schedules and CPR methods is rapidly becoming a moot point as far as the Medicare system is concerned.

The CPR system tends to put a premium on performance of new procedures for which comparative screens have not been established. A physician can charge a high fee for a new procedure and have it reviewed for its reasonableness by a medical review committee. After these fees are established and comparative screens are developed, the new procedure often remains highly rewarded relative to old procedures, because there is little financial incentive for physicians to lower prices as time goes on.

Thus, devices that allow for the performance of such new procedures should be highly valued by physicians, other things being equal. (Note, though, that new procedures may require a coverage decision, which may slow the adoption of such devices by physicians.) Gastroendoscopy is an example of a new device-embodied procedure that was introduced at high fee levels and that is

today highly profitable to physicians who perform the procedure in sufficient volume (448).

New procedures are typically device-embodied, whereas the "thinking services" provided by physicians, even though they may embody advances in knowledge, are generally incorporated in existing procedure categories, such as the office visit. Hence, the bias toward higher rates of return to new procedures generally represents a bias toward device-embodied procedures relative to "cognitive services."

Schroeder and Showstack analyzed four illustrative styles of medical practice, ranging from infrequent to frequent use of laboratory tests that can be performed in the office (277). Physicians' net incomes increase as the intensity of laboratory procedure use increases. To deal with this problem, it has been suggested that uniform benefit or fee schedules should be constructed on a basis other than UCR, perhaps by experts reviewing data on the relative costs of procedures (137, 140). The effect of such a fee schedule on the use of device-specific procedures or the adoption of new ones would, of course, depend on the relative fees actually adopted. Should cognitive services be valued more highly relative to device-specific services, physicians would, other things being equal, have an incentive to spend relatively more of their patient-care time on them.

Payment for Ambulatory Clinical Laboratory Services¹²

Laboratory equipment, supplies, and reagents represent an important and rapidly advancing area of medical devices. Laboratory testing volumes have increased dramatically in the past decade, partly as a result of the development of new tests and automated equipment and partly as a result of third-party payment methods. Between 1972 and 1977, laboratory tests nearly doubled for both hospital and ambulatory care (126). Hospital laboratory test costs increased from \$2.2 billion to over \$4 billion, and out-of-hospital tests increased from 850 to 1,510 tests per 1,000 physician visits (126). During this same period, per capita visits to physicians decreased from 5.0 to 4.8 (126).

¹²The material presented in this section is based on a background paper prepared for OTA by Foster (120).

Payment for clinical laboratory services delivered to hospital inpatients is part of the hospital payment system described above. This section focuses on issues in payment for laboratory services rendered to ambulatory patients.

Laboratory tests are generally ordered by physicians and are commonly offered by three kinds of laboratories: those located in hospitals, those located in physicians' offices, and those independent of both hospitals and physicians' offices. In 1977, there were an estimated 7,200 hospital laboratories, 50,000 to 80,000 physicians' office laboratories, and an estimated 7,650 independent laboratories in the country (226,329,355).

The setting in which testing takes place is determined in part by the economics of laboratory testing. As new automated chemical laboratory technologies came to market in the 1960s, economies of scale in test production favored centralized testing in large independent laboratories, whereas more recently the development of simple new tests such as enzyme immunoassay and microprocessor-based equipment has favored decentralized testing in physicians' offices. But the methods of third-party payment also affect the profitability of testing in different settings and therefore influence the choice of testing location.

Medicare's methods of paying for ambulatory laboratory tests are particularly influential for three reasons: first, Medicare beneficiaries represent a substantial proportion of laboratory test use; second, in many States, Medicaid uses Medicare's payment methods to pay for ambulatory laboratory services; and third, physicians tend to make decisions on the location of testing for their practice as a whole, not on a specimen-by-specimen basis, further increasing the leverage of Medicare program reimbursement decisions.

Medicare's payment method for ambulatory laboratory tests depends both on the setting in which a test is ordered (i.e., whether hospital outpatient department or physician's office) and the setting in which it is performed (hospital, physician's office, or independent laboratory).

Before July 1984, Medicare payments for tests ordered during physician office visits were made on a reasonable-charge basis under Part B, the Supplementary Medical Insurance program. Pay-

ment for these services was 80 percent of the reasonable charge, after the beneficiary had met an annual deductible payment (currently \$75). The reasonable charge for a laboratory test was determined by a CPR method of screening claims similar to that applied to physicians' fees. The reasonable charge for a laboratory test, regardless of where it is performed, is the lowest of the five following separate limitations:

- the *actual charge* billed for the service by the physician or laboratory;
- the *customary charge* of the laboratory or physician for the test, calculated as the provider's median charge in the previous year;
- the *prevailing charge* in the locality, computed as the 75th percentile of all customary charges for all participating laboratories or physicians;
- the lowest *charge* at which the test is widely and consistently available (currently established for 12 common laboratory tests; or
- the *comparable charge* paid by the private insurers that serve as the Medicare carrier.

The customary charges of hospitals, physicians' offices, and independent laboratories, regardless of whether they use automated equipment, were commingled to calculate the prevailing charge in the locality, and all kinds of providers of such services were subject to the same prevailing charge or lowest charge limitation. Note also that this procedure generally resulted in Medicare's paying laboratories at a low rate relative to private insurers.

Medicare can pay one of three different entities for ambulatory tests: the beneficiary, the test-ordering physician who has accepted assignment, or the testing laboratory that has accepted assignment (42 CFR, sec. 405.251(b)). Until a recent change in the law, if the beneficiary sought reimbursement, he or she would receive from Medicare 80 percent of the laboratory's reasonable charge, less any deductible. The party billing the beneficiary (whether it be a physician's office, hospital, or independent laboratory) was subject to no limitation on the amount that could be charged the beneficiary, who had to make up the difference.

Under this method of payment, the physician was in a unique position of having the power not only to choose whether or not to accept assignment and bill Medicare directly, but also whether to perform a test in the office or send the specimen to an independent or hospital laboratory. If the physician accepted assignment, the amount Medicare would pay depended on the information supplied on the physician's claim for reimbursement. If the claim indicated that the test was performed in the office, Medicare would pay the physician 80 percent of the reasonable charge as described above. If the claim indicated that the test was performed by an outside laboratory, Medicare would pay the physician only the laboratory's reasonable charge plus a \$3 handling fee.

Before July 1984, Medicare reimbursement for tests ordered during hospital outpatient visits was based on 80 percent of the cost of the service to the hospital and 80 percent of the reasonable charge for any physician service provided in connection with the test. (The patient was responsible for paying the remaining 20 percent.) Since October 1983, HCFA treated most clinical laboratory tests performed in hospital laboratories not as physicians' services but as hospital outpatient services. Consequently, the price was typically based on the cost, not the charge, method.

In July 1984, Public Law 98-369 established a new method for setting ambulatory laboratory fees that represents a significant departure from the traditional method described above. For a 3-year period beginning in 1984, Medicare payment for laboratory services will be established at a fixed percent of the prevailing fee level (60 percent for physicians' offices and independent laboratories, 62 percent for services to hospital outpatients). After 3 years, a national fee schedule, presumably departing from the prevailing charge, will be developed.

The new law expressly forbids physicians from billing for laboratory services unless they are actually performed in the physician's office. Physicians who conduct their own tests can still choose whether to accept assignment, but the law contains a provision to encourage assignment. When a physician accepts assignment, Medicare reim-

bursement will be at 100 percent of the fee schedule amount (rather than 80 percent) and the coinsurance and deductible will be waived.

Independent laboratories must accept assignment, but Medicare will pay 100 percent of the fee schedule and will waive coinsurance and deductible requirements. The handling fee (currently \$3) will be available to the physician or laboratory that collects the specimen.

Overall, Medicare's payment method for laboratory tests encourages physicians to perform tests in their own offices, especially when the expected per-test profit exceeds the \$3 handling fee (i.e., when the Medicare payment level plus additional payment by the patient exceeds per-test costs in physicians' offices by at least \$3). Whether this condition is met depends on the technical costs of performing specific tests and the strength of economies of scale in their production.

Tests requiring a heavy fixed investment in capital equipment may be economical only for the highest volume group practices. But performing tests in physicians' offices eliminates transportation costs required of outside laboratories and the extra costs associated with laboratory licensure standards, to which physicians are not obligated in most States. The recent emergence of simple, inexpensive laboratory equipment and test kits that can be operated at a profit at low volumes has opened up a wide new physicians' office market that clinical laboratory equipment manufacturers are seeking to fill (35).

The encouragement of testing in physicians' offices, although an important new market for manufacturers, may not be the most rational use of health care resources for two reasons. First, there are situations in which the physician has a financial incentive to select the more costly setting. For example, suppose the fee schedule rate for a test is \$9 and the cost of the test performed in an independent laboratory is \$4.50 (including transportation), while a physician can produce the same test at a cost of \$5. Under both the old and new reimbursement methods, the physician has an incentive to produce the test in-house, regardless of the higher cost. When it is recognized that the physician can refuse assignment on a claim-by-claim basis and charge the patient more than

\$9, the financial incentive to perform the test in the office appears even stronger. Also, by expressly forbidding physicians from billing for services provided by independent laboratories, the new law will further strengthen the incentive for testing in physicians' offices.

Second, there is suggestive evidence that tests performed in physicians' offices maybe of lower quality than are tests performed by independent laboratories (132a,183,212). Data from a national proficiency testing program conducted by the American Association of Bioanalysts revealed that physicians' office laboratories in the program produced substantially less precise and accurate test results than did independent laboratories (132a, '183). However, the introduction of automated laboratory technology may improve physician laboratory performance in the future.

Medicare's payment system also encourages hospitals to expand their laboratory services to outpatients and nonhospital patients. The new prospective hospital payment system, which pertains only to inpatients, creates strong pressures for hospitals to maximize the proportion of their laboratory tests conducted on outpatients in order to allocate as many costs as possible to (and reap as high revenues from) this less restricted payment area. And to the extent that hospitals can compete for business with independent laboratories, this additional source of revenue will further help offset the laboratory-associated costs.

However, Medicare's new laboratory payment system may encourage some hospitals to refer the bulk of their inpatient testing to highly automated independent laboratories with competitive prices in order to reduce inpatient costs. Thus, the role of the hospital laboratory in the ambulatory laboratory testing market appears to be undergoing fundamental changes—with the precise outcome unknown at this time.

Payment for Medical Devices Used in the Home

Medical devices used in the home include a wide range of products—from disposable supplies such as bandaids, incontinence aids, and pregnancy tests, to long-lasting equipment such as wheel-

chairs and hospital beds. Third-party coverage of a device used in the home depends on specific characteristics of the device and the patient. From the standpoint of payment, four different kinds of medical devices are:

- *Self-administered medical devices*—devices such as bandages, incontinence aids, thermometers, blood pressure monitors, or over-the-counter tests. These products are chosen by consumers, not physicians, and most third-party payers do not cover them. There are some exceptions if the devices are prescribed by a physician.
- *Durable medical equipment (DME)*—equipment that can stand repeated use; is generally not useful in the absence of illness; and is appropriate for use in the home. These devices are generally covered, provided they are prescribed by a physician.
- *Home health care devices*—devices used in conjunction with health care services rendered in the home by health care professionals. Medicare and Medicaid cover these devices, but their coverage by private insurers varies.
- *Home renal dialysis devices*—equipment and supplies used to provide home renal dialysis to patients with end-stage renal disease. These devices are covered by Medicare, with supplementary coverage provided by some private insurers.

Self-administered medical devices, if ordered without a prescription, are rarely covered by third-party payers; consequently, they can be considered traditional consumer goods and will not be discussed in detail except to note that the lack of insurance coverage for such devices puts them at a disadvantage relative to devices provided by physicians or other professionals. If these devices are ordered by prescription, they are sometimes covered under insurance policies, usually to the same degree that devices provided in a physician's office would be covered. Self-administered devices will be demanded if their purchase price and the convenience they represent is competitive with the out-of-pocket costs and convenience of using alternative devices that are covered by third-party payers.

Renal dialysis devices used in the home are unique in that they are covered, by a uniform Medicare payment system: Medicare's End Stage Renal Disease (ESRD) program. Since 1972, Medicare benefits have been available to all patients regardless of age. The effect of the payment system on the kinds and prices of available dialysis equipment and supplies, as well as on the settings in which they are used, has been profound. A separate case study prepared for this report examines hemodialysis devices in detail (see box E) (260).

The two other kinds of devices—durable medical equipment and devices provided as part of home health care services—raise some interesting issues for Federal payment policy and are discussed in detail below.

Payment for Durable Medical Equipment

Hospital beds, wheelchairs, oxygen and its related equipment, canes, and crutches are examples of DME. The Inspector General of DHHS has projected total national (public and private) expenditures for DME to reach \$1.26 billion to \$1.58 billion in fiscal year 1985 (160). In 1982, Medicare outlays for DME were about \$310 million (158), up almost 150 percent from \$125 million in 1979 (333).

These estimates do not include durable equipment provided to Medicare patients as part of home health services, estimated at about \$19 million in 1982 (158). Table 20 shows the distribution of spending for various types of DME by a sample of Medicare beneficiaries in 1977. Interestingly, oxygen and oxygen equipment alone accounted for 46 percent of total expenditures for rental and purchase of DME. Medicare expenditures for DME may increase even more with the advent of DRG payment for hospitals. The incentive for hospitals to discharge patients early to the home may lead to greater use of DME in the recovery period.

DME is a distinct benefit category under Medicare's Supplementary Medical Insurance program (Part B of Medicare). Medicare generally covers 80 percent of the "reasonable" charge or cost of

Box E.—Medicare Payment for Renal Dialysis: Effect on Medical Devices¹

End-stage renal disease (ESRD) afflicts about 83,000 people in the United States (98). In the course of treatment for this disease, most patients and their providers use an array of products produced by the hemodialysis equipment and supplies industry. This industry is relatively new. Its whole existence is a consequence of modern medical advances that have made hemodialysis a viable treatment for ESRD.

For patients with ESRD, the major alternative to kidney transplantation is dialysis, which offers an artificial mechanism for performing kidney functions. In *hemodialysis*, blood is pumped from the patient's body, subjected to a process of dialysis, and then returned to the body in a continuous extracorporeal blood loop. Patients on hemodialysis are typically dialyzed three times per week, for sessions ranging from about 3½ to 5 hours each. These patients can be dialyzed at home or in hospital-based or freestanding dialysis facilities or centers. Hemodialysis was the treatment for about 89 percent of the patients with ESRD in 1982 (98).

Another form of dialysis, *peritoneal dialysis*, has been increasing in popularity in recent years. In peritoneal dialysis, the process of dialysis occurs within the patient's body rather than via an extracorporeal blood loop. Continuous ambulatory peritoneal dialysis (CAPD) involves a continuous dialysis process and frees the patient from dependency on a machine. Used by about 10 percent of the ESRD population in 1982, CAPD is the most popular form of peritoneal dialysis (98).

Since July 1973, the Medicare program has covered about 93 percent of the ESRD patient population (78). ESRD patients are enrolled under Parts A and B of the Medicare program. Part A (Hospital Insurance) covers the reasonable and necessary services received in a participating facility, including inpatient dialysis. ESRD patients generally receive dialysis on an outpatient basis, covered by Part B (Supplementary Medical Insurance). Under Part B, ESRD beneficiaries pay a monthly premium and are entitled to payment of 80 percent of reasonable charges or costs above a deductible. Patients are responsible for the remaining 20 percent of charges.

Home dialysis has been covered under this same basic arrangement. Medicare pays 80 percent of allowed costs for supplies and equipment and physicians' services above the deductible. Since 1978, if the patient obtained home dialysis and equipment from an approved facility that reserved the equipment for the exclusive use of patients on home dialysis, the 20-percent coinsurance requirement has been waived.

In establishing the actual levels of payment for dialysis, the Medicare program had few precedents. The early decision was to pay 80 percent of the average cost to a hospital-based dialysis facility, and 80 percent of the reasonable charges for a freestanding dialysis facility up to a screen (or limit) of \$133 per treatment. If routine laboratory services were included, the screen was raised by an additional \$5; if the supervisory services of a physician were included in the facility's costs, the screen was increased by \$12, to \$150. These rates were in effect from 1974 until August 1983, when they were supplanted by a new reimbursement method.

In 1982, prior to the new rules, nearly all freestanding facilities were being paid at the rate of \$138 per treatment (78). Most hospital-based facilities requested and were granted exceptions to the screen, on the grounds that their costs were higher; the average hospital-based payment in 1982 had risen to approximately \$170 per treatment (78,356).

Under the old system, physicians could choose from one of two systems of payment: the initial method and the alternative reimbursement method. Under the initial method, reimbursement for supervisory care was paid to a facility as part of its reimbursement rate. Other nonsupervisory services were paid on a fee-for-service basis. Under the alternative method, physicians were paid a comprehensive monthly fee per patient. For patients dialyzed in facilities, this fee was based on a calculation of the customary or prevailing charges for a followup visit, multiplied by 20. For supervision of home patients, the weighting factor was set at 14 rather than 20, to reflect the presumed lower requirements of home patients for physician supervision.

Section 1881 of the End Stage Renal Disease Amendment of 1978 (Public Law 95-92) established a new prospective reimbursement method for dialysis facilities. The final rules under this system, which became effective August 1, 1983, established average payment rates of \$131 for hospitals and \$127 for freestanding facilities regardless of whether dialysis occurs in the center or at home (316). (Adjustments were made for geographical wage differentials.)

Fixed rates such as these are designed to encourage facilities to control costs. Any excess of the rates over incurred costs can be kept by the facility; any deficit in costs must be absorbed. In addition, the composite nature of the rates is intended to create an incentive for movement toward increased home dialysis. One way for a facility to reduce costs is to lower the cost of materials and equipment used in the dialysis process. This can be accomplished by pressuring manufacturers to lower the prices they charge. In general, there has been little upward movement in prices in this market, and prices for at least one key product, dialyzers, have actually fallen (260). However, variation remains in prices paid by users. More concerted efforts by buyers are likely, through more strenuous bargaining, forming co-operative buying ventures, or other means.

Materials costs can also be reduced by increased use of dialyzers. The practice of reusing dialyzers has grown rapidly in recent years. About 25 percent of the freestanding facilities reuse dialyzers, compared with only 1 percent of the hospital-based facilities (78). Although manufacturers state that today's dialyzers were designed for single use only (457), reuse is a fact. Cost pressures may stimulate design changes that enhance the efficiency or reduce the costs of reprocessing. Also, because reuse raises a facility's labor costs by requiring extra handling of dialyzers, manufacturers may be stimulated to develop automated dialyzer reprocessing equipment.

The incentive for home dialysis under the new rules should create some movement toward increased home dialysis. What effects would this have on the industry? If the movement was simply from in-center hemodialysis to home hemodialysis, the effects would probably increase sales. Equipment and disposables requirements would be technically similar. However, patients at home would not be able to share machines as they would in facilities. Without this opportunity to economize on machines, more machines would be demanded for any given patient population.

However, most new home patients are choosing CAPD (40), although not all ESRD patients can use this modality. Firms that have a firm foothold in the market may gain at the expense of others that do not. At the same time, many firms focusing on hemodialysis will be encouraged to diversify into CAPD products (186,271).

¹The material presented is based on a case study of the hemodialysis equipment and supplies industry prepared for OTA by Romeo (260).

this equipment, subject to the annual deductible amount. In practice, the reasonable charge is determined by the CPR method described in sections above. The allowed rate of payment for a particular item of DME is the minimum of the DME supplier's actual charge, the supplier's customary charge (the median of supplier's own past charges) or the prevailing charge, defined as the 75th percentile of all purchase or rental charges for the particular device in the locality during the preceding year. 13

¹³The DME reimbursement system is currently under scrutiny by HCFA and the General Accounting Office for its effects on users' decisions whether to purchase or rent equipment (92, 156, 157, 237

If the supplier agrees to accept the Medicare reasonable charge as payment in full (i. e., accepts assignment), then the Medicare enrollee is liable only for his or her 20-percent coinsurance plus any deductible owed. But if the supplier does not accept this payment, the beneficiary must pay the difference between the reasonable charge and the

333Uncertainty about the duration of use of DME is inherent in the nature of the service, but Medicare's current system of payment provides inadequate incentives for users to purchase equipment, even when it is fairly clear that such a decision would cost Medicare less than rental. Although the issue has important implications for Medicare expenditures, it does not influence choices among devices or the overall rate of use of devices in any fundamental way and is not discussed in this report.

Table 20.—Durable Medical Equipment (DME) Rental and Purchase Reimbursement Expenditures, by Major Category, All Participating Carriers, 1976 and 1977^a

Category description	1976				1977			
	Rental		Purchase		Rental		Purchase	
	Dollars	Percent	Dollars	Percent	Dollars	Percent	Dollars	Percent
Hospital beds and accessories	\$1,591,925	26.530/o	\$ 520,023	9.85%	\$ 798,338	19.430/o	\$ 867,895	13.81 o/o
Commode chairs, bedpans, urinals, and toilet accessories.	232,862	3.88	158,948	3.01	148,765	3.62	218,369	3.47
Canes, crutches, and accessories	31,149	0.52	31,656	0.60	33,919	0.83	24,887	0.40
Traction equipment and accessories	175,114	2.92	77,044	1.46	75,780	1.84	108,429	1.73
Walkers and walking aids.	202,821	3.38	170,110	3.22	151,566	3.69	172,573	2.75
Wheelchairs and accessories	1,091,624	18.19	536,966	10.17	736,903	17.93	644,866	10.26
Oxygen.	—	0.00	2,598,333	49.21	—	0.00	2,323,585	36.98
Pads and cushions	147,831	2.46	25,911	0.49	45,628	1.11	91,427	1.45
Miscellaneous DME.	16,570	0.28	18,077	0.34	188,614	4.59	19,450	0 . 3
Oxygen therapy equipment	1,963,170	32.72	816,872	15.47	1,183,791	28.81	1,349,534	21.48
Repair/maintenance	347,758	5.80	40,611	0.77	344,094	8.38	36,201	0.58
Unspecified DME	199,920	3.33	285,558	5.41	401,552	9.77	426,464	6.79
Total	\$6,000,744	100.01/o	\$5,280,109	100.00/o	\$4,108,950	100.00/o	\$6,283,680	100.01 o/o

^aData not included from Equitable Tennessee for 1977 or from Washington Physicians Service from Nov 1 through Dec. 31, 1977.

SOURCE T J Janssen and G T Saffran. "Reimbursement for Durable Medical Equipment," *Health Care Finan. Rev.* 2(3):94, winter 1981

actual price of the equipment. The decision whether to accept assignment rests with the supplier on a case-by-case basis.

In addition to being generally inflationary, Medicare's CPR pricing system creates particular problems in localities with only one or a few suppliers of DME. A high-priced supplier with at least 25 percent of the locality's market for a particular kind of DME can unilaterally determine the prevailing charge and thus manipulate its payment rate (237). The only deterrent to such behavior is the 20-percent coinsurance rate, which may make some consumers sensitive to the price charged. But in localities with just one or two suppliers, this price sensitivity is bound to be low.

Some observers have noted the potential impact of Medicare's hospital DRG payment system on the suppliers of DME (154). Under DRG payment, hospitals have an incentive to become suppliers of services and products that are subject to less restrictive payment. One potential is for these institutions to become DME suppliers. Having a built-in referral base of patients would facilitate this kind of service integration.

The net effect of competition from hospitals on DME prices is unknown, but it could conceivably cause price cutting by freestanding suppliers in an attempt to maintain their market share. However, the sensitivity of patients to changes in DME prices may be low because the effective coinsurance rate for DME in 1977 was estimated at 26 percent (237). Independent suppliers appear to be concerned about the possible effects of competition from hospitals with a "captive" market (161) and have suggested that Medicare require hospitals to provide patients with information on independent suppliers.

Payment for Home Health Care Services

Home health care services are defined as services that require professionally trained personnel (e.g., nursing, physical therapy) and are delivered to patients in the home. To some extent, home health care substitutes for institutional care provided in hospitals and nursing homes, but in part it is also a service that substitutes for care that would otherwise be provided by family, friends, or patients themselves. Since medical devices are

commonly used in the delivery of these services, the recent rapid growth in the use of home health care services will affect the kinds of devices that will be demanded.

Although there are no precise data on historical trends in the total use of home health care services throughout the country, data are available for use by Medicare and Medicaid beneficiaries. From 1974 to 1982, the number of home health visits to Medicare beneficiaries increased by 247 percent, from 8.1 million visits in 1974 to 28.1 million visits in 1982 (159). In the same period, Medicare reimbursements to home health agencies—organizations that provide home health care services—grew from 1.2 to 2.5 percent of total Medicare reimbursements, or \$1.2 billion in 1982. Approximately 4 percent of those reimbursements were for equipment, appliances, and nonroutine supplies offered as part of home health care visits (136), and 28 percent can be attributed to non-labor costs (310). Medicaid expenditures for home health services were almost \$500 million in 1982 (399).

Table 21 estimates national home health care expenditures by source in 1981. Since the data underlying these estimates are imprecise, the table should be considered only as a general description of the relative importance of various funding sources. Almost 60 percent of home health care expenditures are paid for directly by patients. Medicare and Medicaid account for another 19 percent of such expenditures, and private inser-

table 21.—Estimated Home Health Care Expenditures and Percent Distribution by Source, 1981

	Dollar amount (billions)	Percent of total
Patient direct payments	\$3.8	58.5%
Medicare	0.9a	13.9
(Federal)		
(State)	0.3	(3.1)
Other government		4.6
Private health insurance	1.1 ^b	16.9 ^b
Philanthropy	0.1	1.5
Total	\$6.5	100.00/0

^aThis is an understatement because it includes approximately one-tenth of expenditures provided through hospital-based home health care services.

^bA proxy was used for expenditures for home health care. The proxy used, reimbursement for "other payment services," generally reflects government and patient direct payments for home health care, but may not accurately reflect private health insurance coverage, which is probably much lower than the 16.9 percent indicated in the table.

SOURCE R. M. Gibson and D. R. Waldo, "National Health Expenditures, 1981," *Health Care Finan. Rev.* 4(1):1-35, September 1982

ance for less than 17 percent. These data are for 1981, before expanded Medicare home health benefits as mandated by the Omnibus Budget Reconciliation Act of 1980 (Public Law 96-499) were implemented. Medicare's share of home health care expenditures may have increased since then.

The number of home health agencies has grown dramatically in the past 3 years alone. Table 22 shows the number of Medicare-certified home health agencies by type in 1979, 1981, and 1982. Substantial growth occurred in the number of proprietary agencies serving Medicare patients. Part of the reported growth between 1981 and 1982 does not represent development of new agencies but is an artifact of the liberalization of Medicare's policy regarding certification of proprietary agencies that went into effect in October 1981 pursuant to the Omnibus Budget Reconciliation Act of 1980. But even between 1979 and 1981, when proprietaries were unable to participate in Medicare in certain States, the number of these agencies serving Medicare patients grew by almost 75 percent.

Medicare will pay for home health services to patients who are homebound, under the care of a physician, and requiring part-time or intermittent skilled nursing care or physical or speech therapy. There are no deductibles or coinsurance required of the beneficiary, and since 1980, there are no limits on the number of visits the beneficiary can receive during any year. Medicare reimburses home health agencies on a reasonable cost basis, much the same as the Medicare inpatient

hospital reimbursement method prior to the introduction of DRG payment. In the recent past, attempts to control Medicare outlays for home health services have centered on two strategies: 1) tight control over eligibility for home health care services, and 2) imposition of per-visit limits on rates of reimbursement to home health agencies.

To be eligible for home health care benefits, the patient must require "intermittent" skilled nursing care. The definition of skilled nursing care depends on the licensing requirements of the individual States; usually it means a person with a Registered Nurse or Licensed Visiting Nurse or equivalent degree. The definition of "intermittent" has been the major avenue for control. HCFA has recently interpreted it to mean a requirement for up to two or three visits per week and less than 8 hours in any one visit. Daily visits by a skilled nurse are reimbursed only if a physician affirms that such frequent visits will not be necessary for more than 2 or 3 weeks (74). The idea is that if a patient needs daily care, he or she should be in a skilled nursing home, even if the person would prefer to stay at home, because it is less expensive (162).

Medicare does not provide home health care benefits to patients who receive total parenteral or enteral nutrition therapy at home. But, since 1977, Medicare has covered these services under its prosthetic device benefit (Part B), which covers all nutrients, equipment, and supplies. HCFA has interpreted the prosthetic device benefit as requiring the patient to have severe and permanent impairment and as not covering the nursing serv-

Table 22.—Medicare-Certified Home Health Agencies by Type of Agency

Type of agency	December 1979	September 1981	December 1982
Visiting nurses association	511	513	517
Combination (government/voluntary) . . . ,	50	55	59
Government	1,274	1,234	1,211
Rehabilitation center based ,	NA ^a	11	16
Hospital based	349	432	507
Skilled nursing home based	NA ^a	10	32
Proprietary	165	287	628
Private nonprofit	44.3	547	632
Other	66	38	37

^aNA indicates information not available; home agencies in these categories were classified as "other" in 1979.

SOURCES 1979 data: U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstration, *Medicare: Use of Home Health Services, 1980*, prepared by Kathryn D. Barrett, July 1983 draft 1981, 1982 data: *Home HealthLine*, "Changing Face of Medicare Home Health" (table), vol VIII, p. 28, Feb 4 1983



Photo credit: American Society for Parenteral and Enteral Nutrition, Inc.

This portable parenteral nutrition system, which pumps nutrients directly into the bloodstream, is being used by a woman in her home. Medicare pays for parenteral nutrition therapy provided in the home only for people with permanent impairment.

ices, delivery charges, or refrigerator for nutrient storage. Some home health agencies have complained that these restrictions shift potential nutrition services away from them to suppliers of Part B services, such as retailers of such medical

equipment and supplies, and also discriminate against patients requiring home health care as well as nutrition services (153). (See box F for a description of the parenteral and enteral nutrition market.)

Control over rates of reimbursement to home health agencies was initiated in 1981 (310) and tightened again in 1981 and 1982. The control was in the form of limits on per-visit routine costs of home health agencies. At present, all home health agencies are subject to a per-visit limit set at the 75th percentile of costs of freestanding agencies, weighted by the mix of visits made (skilled nursing, physical therapy, home health aids) and the urban or rural location of the agency. The cost of medical equipment, appliances, and supplies that are not routinely furnished in conjunction with patient care visits are not subjected to the limits.

The reimbursement limits have several inherent incentives. The most obvious is for the home health agency to "unbundle" its supplies from routine categories to nonroutine categories, which are not subject to payment limits. The second is to substitute nonroutine equipment, appliances or supplies for routine nursing or other services whenever possible. Third, the agency has no incentive to consider price in decisions to purchase nonroutine items. The ultimate effect of these limits is probably to increase the use and cost of medical devices in home health care.

¹⁴Medical supplies that are not routinely furnished in conjunction with patient care visits and are directly identifiable services to an individual patient must meet the following criteria: 1) the common and established practice of home health agencies in the area is to charge separately for the item; 2) the agency follows a consistent charging practice for both Medicare and non-Medicare patients receiving the item; 3) generally, the item is not frequently furnished to the patient; 4) the costs can be identified and accumulated in a separate cost center; and 5) the item is furnished at the direction of the patient's physician and is specifically identified in the plan of treatment (310).

Box F.—Parenteral and Enteral Nutrition Therapy

Parenteral and enteral nutrition are relatively recently developed medical technologies that depend on medical devices for their use. Parenteral nutrition refers to the intake of nutrients directly into the bloodstream, circumventing the digestive tract. Enteral nutrition refers to the intake of nutrients into the stomach or small intestine via a catheter or nasal tube (10). Enteral nutrition is the preferred approach for persons who retain the use of their lower alimentary tract because it is both safer and cheaper than parenteral nutrition (59). Sometimes referred to as hyperalimentation, these technologies have as their primary goal the elimination of malnutrition in those patients who cannot adequately digest food or whose nutritional needs are elevated due to injury or disease.

For parenteral nutrition, the infusion setup consists of the nutrient solution; nondisposable equipment, such as the intravenous (IV) pole and infusion pump; and disposable supplies, such as the IV administration set and infusion cassettes. Prior to the late 1960s, prolonged maintenance of patients who could not adequately digest food was not possible. The development of hyperalimentation came about through advances in four areas: greater knowledge of human nutritional needs, improved surgical procedures for insertion of catheters, improved catheter composition and design, and improved infusion control devices.

Parenteral and enteral nutrition can be delivered either in the hospital or, when the conditions are right, in the home. In either setting, they represent expensive therapies, especially in the long term. Rough estimates of 1982 per-patient charges for these therapies are as follows (10):¹

	<i>Parenteral</i>		<i>Enteral</i>	
	<i>Home</i>	<i>Hospital</i>	<i>Home</i>	<i>Hospital</i>
Charges per day	\$125-\$250	\$300-\$600	\$30-\$60	\$150-\$300

The most important factor in cost appears to be the quantity of disposable supplies, including nutritional solutions which account for almost 90 percent of the total cost. Other studies have estimated costs of a typical parenteral patient at home to be about \$40,000 to \$50,000 per year (147,189,283). A recent study of Medicare reimbursements for home hyperalimentation revealed substantial variation among sampled patients in the amounts billed by suppliers and paid by Medicare. For parenteral nutrition, the amounts billed by suppliers ranged from \$3,046 to \$4,122 per month, and enteral nutrition billings ranged from \$346 to \$1,130 per month (162).

Estimates of the number of patients receiving hyperalimentation nationally are imprecise but have been approximated for 1982 as follows (10):

	<i>Parenteral</i>		<i>Enteral</i>	
	<i>Home</i>	<i>Hospital</i>	<i>Home</i>	<i>Hospital</i>
Number of patients	2,000-5,000	200,000	5,000	2,000,000

Major issues involving payment policy are currently outstanding and have an important impact on the amount and location of hyperalimentation services. Payment for these technologies in the hospital is straightforward. Most third-party payers, including Medicare and Medicaid, pay for hyperalimentation as they do for any service delivered to inpatients. In 1977, Medicare began to cover home hyperalimentation on the advice of the Public Health Service. Because IV nutrients are classified as drugs and are therefore not individually reimbursable under Medicare's Part B (Supplementary Medical Insurance) benefit, the Medicare program declared all of home hyperalimentation a prosthetic device and therefore subject to Part B coverage. However, the prosthetic device benefit is generally reserved for those with permanent impairment and therefore does not cover those with temporary need for this technology. The Health Care Financing Administration is currently considering liberalizing the definition of permanent impairment to include long-term disabilities, but proponents of home hyperalimentation claim that this will still deny home coverage to those with short-term problems.

For example, patients requiring surgery who have lost more than 20 percent of their body weight generally represent higher surgical risks and may benefit from a short course of hyperalimentation prior to the operation (290). These patients would not be covered for hyperalimentation in the home and would most likely receive such services in the hospital prior to surgery. However, since hyperalimentation is an expensive therapy, its use in the hospital may also be discouraged by Medicare's new per-case payment method based on diagnosis related groups (DRGs).

The use of hyperalimentation as an adjunct to cancer therapy illustrates the difficulties facing those who make payment policy. Under what conditions and for what kinds of patients is hyperalimentation effective and safe and therefore worthy of payment? At present there is a great deal of controversy over the effectiveness of nutrition support in cancer patients except to assist in the recovery from side effects of anticancer therapies (such as radiation enteritis) (44). Under DRG payment, hospitals can be expected to become more conservative in the application of the technology, given its high daily cost. Lacking home coverage, patients (or their physician advocates) would also be conservative about its use in marginal situations. However, if Medicare covered short-term nutrition support, the procedure might be used more frequently for indications for which definitive medical benefit has not been established.

¹These are rough estimates only; they are not based on primary data collection.

THE FINANCIAL RELATIONSHIP BETWEEN THE THIRD-PARTY PAYER AND PROVIDERS

The vast majority of health care services in the United States are delivered by private providers—hospitals, physicians, and other professionals and institutions—who are organizationally and financially independent of the third-party payer. As discussed above, these providers bill either the patient, the third-party payer, or both and are paid some proportion of their costs or charges, depending on the payment methods and policies of the third-party payer. This fee-for-service system pays providers more when more services are delivered. Except for those services whose level of payment is below their cost,¹⁵ the provider is financially rewarded by providing more services. Although the third-party payer can attempt to control the use of services through regulatory means, such

as utilization review, the provider has a general incentive to deliver more individually billable services.

There are two exceptions to this fiscal independence of payer from provider. First, for health services that are provided directly by the government in publicly owned and operated facilities, the payer and provider are integrated in the same entity. The VA's system of hospitals, nursing homes, and outpatient clinics is an example of an integrated health care system that is relatively closed and publicly funded and operated. Second, a small but growing proportion of the population is enrolled in per capita insurance plans.

Public Systems

Whether the patterns of use of health care services and hence, of the devices on which many of them depend are substantially different in publicly operated and budgeted facilities is a matter for empirical investigation. There is some circumstantial evidence suggesting that the rate of adoption of certain new medical devices has been

¹⁵There are several reasons why the level of payment might be below the cost of providing a service to a given patient. First, the cost of providing the service might vary randomly around some mean level, thus leading to losses on some patients which are made up for by profits on others. Second, the service might be a "loss-leader," deliberately priced low to encourage utilization of other, more profitable services. Third, the provider may be required to offer some services below cost as a condition for providing others to a third-party payer's beneficiaries.

slower in VA hospitals than in the civilian health care sector, but differences between public and private administration confound the comparison. VA hospitals adopted CT scanners much more slowly than other hospitals of comparable size. In 1980, almost 85 percent of all community hospitals of 500 beds or more had at least one CT scanner, whereas only 25 percent of VA hospitals of comparable size had adopted CT scanning (349).¹⁶ In the remaining hospitals, the VA contracted with civilian hospitals for provision of CT procedures.

The rate of use of therapeutic apheresis also appears to be substantially lower in VA hospitals than in the civilian sector, although no comparisons by type of patients treated are available to pursue the reasons for the difference (350). A study conducted in the early 1970s of hospitals' adoption of respiratory therapy techniques and electronic data processing found that Federal hospitals adopted these technologies more widely than non-Federal hospitals, but the study did not control for hospital size, the population served, and other important differences between Federal and non-Federal hospitals (187). (Federal hospitals on average are much larger than non-Federal hospitals.)

Per Capita Payment Systems

The second exception to the fiscal independence of payer and provider covers a small but growing proportion of the population (5.8 percent in January 1984 (170)) enrolled in health maintenance organizations (HMOs). For a fixed per capita payment, HMOs provide comprehensive but specified covered medical services through a defined set of physicians and hospitals (346). An HMO may either employ or contract with physicians to provide the covered services. If the relationship is contractual, it may be on a basis other than simple fee-for-service. Although an HMO may own its hospital, almost all contract with selected hospitals and other facilities to provide services to their enrolled members. Since the HMO must compete with other insurers, it has an incentive to keep premiums competitive with them. HMOs

are also organizationally well suited to limiting costs by controlling the use of covered services.

There is strong evidence that enrollees of prepaid group practices, a type of HMO organized around a medical group practice, have lower rates of hospitalization than other plans. In a review of HMO experience, Luft concluded that enrollees in prepaid groups had about 30 percent fewer hospital days, mainly because of lower admission rates rather than shorter lengths of stay (198). But studies of HMOs organized around contracts with independent physicians, frequently referred to as individual practice associations (IPAs), do not support the contention that these have lower hospitalization rates when differences among patient characteristics are considered (346). In general, IPAs and other HMOs appear to have lower rates of surgery than fee-for-service plans (346).

The lower rates of hospitalization in prepaid groups would, of course, lower the use of medical supplies and equipment in the hospital. Surgical supplies and equipment, in particular, would need to be bought less frequently under an HMO payment system. Of course, to some extent reductions in the use of hospital devices may be accompanied by more intensive use of device-embodied procedures during ambulatory care visits,

The net effect of these shifts has not been studied, but it is likely that the direct impact of HMOs to date on the medical devices industry or any of its segments is probably small.¹⁷ Although the competitive effect of HMOs on the behavior of other private insurers could reduce the rate of use of health services more generally in the community, particularly in those metropolitan areas where HMOs have a significant share of the insurance market, there is no convincing evidence that such an effect has occurred (198). This result is not surprising considering that HMOs, as well as other plans, have been operating in an environment where the buyers of health insurance

¹⁶Most VA medical centers, for example, include chronic care beds, whereas most community hospitals do not.

¹⁷As of January 1984, 5.8 percent of the civilian population was enrolled in HMOs, and in 1981, about 84 percent of HMO enrollees were in prepaid group practices (170). If prepaid group practices account for a 30-percent reduction in days of stay per capita, the existence of prepaid group practices is responsible for at most a reduction of 1.5 percent in total patient days.

and medical care are insulated from market pressures to be efficient.

The appeal of HMOs and other prepaid plans is that they hold promise for more careful assessment of all inputs into the production of health care services, including devices. HMOs have incentives to provide care in the most efficient and cost-effective manner, using the best mix of resources to accomplish that purpose. But there are

also pitfalls. HMOs have an incentive to enroll healthy members of the population whose medical care is less costly to provide. Such practices also have a financial incentive to provide as few services as possible to their enrollees. As long as HMOs exist in an environment in which they must compete for members, however, the tendency toward underprovision of services maybe limited.

DISCUSSION AND POLICY OPTIONS

This chapter has examined the relationship of third-party payment, particularly Medicare, to the overall size of the medical devices market and the kinds of medical devices that are likely to be bought and used. In the traditional fee-for-service sector of U.S. health care, the decision to cover a particular device and the methods used to determine the amount of payment appear to influence the demand for devices.

The methods used to determine levels of payment for devices or device-embodied medical services have influenced their adoption and use in ways that will increase society's cost without adequate concern for benefits. In particular, the reasonable charge approach used by Medicare for all Part B services creates problems in several areas. With physicians' services it tends to favor new device-embodied procedures over traditional technologies and office visits, with inadequate regard for their relative cost effectiveness. For laboratory testing, the CPR mechanism tends to encourage laboratory testing in physicians' offices. And for durable medical equipment, suppliers with a high share of the market may be able to manipulate payment rates.

Although cost-based reimbursement of hospitals is being largely discarded by Medicare, and may soon disappear for other payers as well, the continuation of cost-based reimbursement of hospital capital tends to favor medical equipment over other kinds of resources used in the delivery of hospital services. In addition, the cost-based system continues to apply to Medicare home health services, creating incentives to use medi-

cal devices (as well as other inputs to home health services) that may be socially inefficient. Although Medicare has instituted limits on per-visit costs, they do not include nonroutine supplies, equipment, and appliances provided as part of a physician's plan for home health services. Thus, there are additional incentives for home health care to become too device-intensive over time.

It appears that the manufacturers of medical devices may be responsive to changes in third-party payment policy, particularly Federal payment policy, in the kinds of devices that are made and the prices at which they are sold. Even in concentrated markets, such as that for hemodialyzers, manufacturers appear to have been responsive to market pressures by reducing prices or improving products to enhance their productivity (260). The recent introduction of Medicare's DRG payment system may lead to substantial changes in the kinds of devices that are marketed to hospitals. The ultimate impact of these changes on the total market for medical devices is, of course, unknown—as are their ultimate effects on the quality and costs of medical care.

The problems discussed above can be addressed on a piecemeal basis by altering details of third-party payment methods, or they can be addressed by broader reforms of the payment system. The options discussed in this section begin with those addressing specific issues raised in four areas of payment: clinical laboratory services, home health services, physicians' services, and hospital services. Options related to more fundamental changes in the health care payment system are then discussed

Payment for Laboratory Testing

Physicians have financial incentives to order and perform clinical laboratory tests in their offices. The solution to this situation is the development of payment methods with neutral financial incentives for physicians to order diagnostic procedures and to select the least costly settings of test performance.

Option 1: Mandate that Medicare establish a laboratory fee schedule with mandatory assignment for all providers.

Medicare's new fee schedule for laboratory services lowers Medicare's payment for tests, but it may strengthen physicians' financial incentives to conduct laboratory tests in their own offices, even when office tests are more costly than tests sent to independent laboratories.

A fee schedule system that on the one hand requires mandatory assignment of laboratory claims by physicians and on the other allows the physician to bill for services even when they are provided by outside laboratories would give physicians a financial incentive to perform their own laboratory tests only when the tests are less costly to perform in the office than in an outside laboratory.

The fee schedule could be based on the price typically charged by laboratories to physicians. This price is usually competitive, especially in metropolitan areas.

This option would eliminate incentives to perform tests in physicians' offices when they are more costly than sending them out, but it would not necessarily eliminate the financial incentive that physicians have to increase test ordering. If the physician must accept assignment, whether a test is profitable will depend on the difference between the fee allowed by Medicare and the lowest cost at which the physician can provide the service. Careful and constant attention would need to be given to the relationship between prices of tests and efficient production of laboratory services because some tests will continue to be profitable and others may become profitable as new technologies reduce laboratory costs.

Option 2: Mandate that Medicare experiment with other alternatives to the reasonable charge method for clinical laboratory services.

A national fee schedule is just one of the alternatives to the reasonable charge methodology for clinical laboratory services. For example, competitive bidding, negotiated rates of payment, and master contracts have been discussed or implemented by State Medicaid agencies. At present, there is insufficient evidence to assess which of these or other approaches is the most effective approach to purchasing laboratory services for Medicare beneficiaries.

The 1981 Omnibus Budget Reconciliation Act (Public Law 97-35) authorized States to enter into competitive bidding or other similar arrangements to procure laboratory testing for Medicaid populations. A State must demonstrate that laboratory services will be adequate, that selected laboratories will be Medicare-certified, and that no more than 75 percent of the business of the winning laboratory is reimbursed by Medicare and Medicaid. To date, only Nevada has implemented competitive bidding for laboratory services (120).

California is considering development of a "master contract" with terms spelled out and reimbursement rates set. The contract would be offered to any licensed or certified laboratory wishing to provide services to California Medicaid enrollees.

HCFA has had under consideration several demonstration projects to test varying methods of laboratory reimbursement. HCFA plans to test four different procurement approaches through demonstration projects: payment rates established by negotiation with laboratories; fee setting by HCFA without negotiation; competitive bidding with laboratories eligible to provide services as long as they agree to accept the price of the winning bid; and competitive bidding with only winning bidders eligible to provide Medicare testing. Currently, HCFA is awaiting the report of a contractor for design of a competitive bidding methodology (120). It remains to be seen whether the demonstration will actually be undertaken.

The Administration has proposed legislation to authorize the Secretary of Health and Human

Services to purchase Medicare laboratory services by competitive bidding, negotiated payment rates, or exclusive contracts with laboratories (S. 643, H. 2576). Because little is known about the feasibility or impact of these approaches, it seems premature to engage in them on a nonexperimental basis.

Payment for Devices Used in the Home

Medicare reimburses for medical devices used in the home through the durable medical equipment benefit (Part B), the prosthetic devices benefit (Part B), and the home health services benefit (Parts A and B).¹⁸ There are several problems in existing payment methods that may affect the kinds of devices that are used and the prices at which they are offered. Moreover, lack of coordination among these benefit categories creates anomalies in payment for different patients using the same devices.

Option 3: Mandate that Medicare include in per-visit payment limits on home health services the cost of nonroutine equipment and supplies.

Cost-based reimbursement of home health care services creates problems of inflation and inappropriate use of all inputs, including devices. For this reason, Congress has authorized DHHS to limit per-visit rates of reimbursement for routine services to the 75th percentile of the costs of free-standing agencies (those not affiliated with institutions) in similar circumstances. At present, however, the cost of medical equipment, appliances, and supplies that are not routinely furnished in conjunction with patient care visits are not subject to the the limits. This exclusion creates incentives for agencies to “unbundle” their supplies from routine categories to nonroutine categories and to substitute nonroutine equipment, appli-

ances, or supplies for routine nursing or other services whenever possible. Moreover, a home health agency has no incentive to consider price in decisions to purchase nonroutine items.

Integrating nonroutine items into the per-visit limits would eliminate these problems, but it would also increase the already existing incentives for home health agencies to select as clients patients whose need for such items is relatively low. Without a reliable measure of case severity, the potential for such patient selection strategies would probably be high. Therefore, an important priority for research would be development of a patient classification system for home care similar to the DRG system used for hospitals. Even then, there is the question of whether home health agencies are large enough to spread the risk of enrolling patients with high equipment needs across a large enough pool of patients.

Option 4: Encourage Medicare to experiment with alternatives to reasonable charge reimbursement of durable medical equipment (DME).

As with other Part B services, the use of reasonable charge screens—maximum limits on the amount Medicare will pay based on comparative profiles of suppliers’ actual charges—for DME probably raises the prices paid for such equipment. Medicare’s CPR pricing system for DME creates particular problems in localities with only one or a few suppliers of DME, where a high-priced supplier with at least 25 percent of the locality’s market for a particular kind of DME can unilaterally determine the prevailing charge and thus manipulate its payment rate.

Possible alternatives to the CPR pricing system would be national or regional price ceilings and competitive bidding by suppliers. As yet, there is no experience with either of these approaches, so it is unknown how they would affect the availability or prices of DME. Price ceilings based in the beginning on regional or national average prices and adjusted for general inflation over the years would tend to raise prices charged by low-priced suppliers while at the same time lowering those of high-priced suppliers. It might also reduce the access of Medicare beneficiaries, particularly those with low incomes, to DME if assign-

¹⁸The Medicare Program has two parts: Part A, the Hospital Insurance program; and Part B, the Supplementary Medical Insurance plan. Part A’s primary purpose is to provide protection against the costs of inpatient hospital care. Other Part A benefits include posthospital extended care services, home health services, and inpatient alcohol detoxification services. Part B services include physician services, outpatient hospital services, outpatient physical therapy, and other ambulatory services and supplies, such as prosthetic devices and durable medical equipment. Part B also covers home health services for those Medicare beneficiaries who have only Part B coverage (345).

ment rates were to drop as a consequence of the ceilings or if suppliers in high-cost localities were to find it unprofitable to serve Medicare beneficiaries.

Unless this approach were adopted in conjunction with a requirement that suppliers of DME beneficiaries accept assignment or elimination of the 20-percent coinsurance requirement for those accepting assignment, the drop in assignment rates would cause part of the burden of expenditure to shift from Medicare to the beneficiary.

Competitive bidding by suppliers would be most useful in areas with a reasonably large number of potential suppliers. The details of a competitive bidding strategy are important in determining the effect on availability and prices of DME. One approach would be a Medicare requirement that all DME rentals or purchases in a locality be made through the two or three low-bidding suppliers. This approach would probably be successful in driving down prices in the near term, but it has certain drawbacks. First, the bidding would have to be on a product-by-product basis, and it would be impractical to require a beneficiary to use a different supplier for each device bought. Second, the approach could lead to a reduction in the number of suppliers, with consequent increases in prices by remaining suppliers in subsequent years.

The effect of any of these approaches on the price and availability of DME to Medicare beneficiaries could be studied in the context of demonstrations or experiments.

Option 5: Extend Medicare home health benefits to individuals on parenteral or enteral nutrition.

Medicare currently refuses to provide home health care benefits to patients who receive at home total parenteral or enteral nutrition therapy—methods of direct feeding through the bloodstream or gut. Since 1977, Medicare has covered these services as a Part B benefit under prosthetic devices. HCFA has interpreted the prosthetic device benefit as applying only to patients with permanent impairment and as excluding any nurs-

ing services. However, as part of training and adjustment for home parenteral and enteral nutrition, nursing services may be required. Patients must receive these services at outpatient departments for nursing services to be reimbursed.

The effect of this regulation is to limit parenteral and enteral nutrition benefits to ambulatory patients with permanent need for the technology. It might be possible to shift patients out of hospitals into home care settings if these restrictions were lifted. However, if home health benefits were extended to patients receiving parenteral and enteral nutrition, the current 20-percent coinsurance rate would no longer apply because home health services (Part A) do not entail coinsurance, and Medicare would bear the full burden of expenditure. To avoid this added cost to Medicare, Congress could authorize DHHS to maintain the relevant equipment and supplies costs as prosthetic devices under Part B, while offering home health benefits under Part A. Patients receiving such services would then be required to copay for the Part B portion but not for the home health services.

Payment for Physicians' Services

Medicare and some other third parties pay for covered physicians' services on a reasonable charge basis. These systems, based as they are on profiles of physicians' charges, tend to have an inflationary effect on physicians' fees because each physician's future payment is tied through the fee screen to currently billed charges. In addition, these systems put a premium on the performance of new procedures for which comparative fee screens have not been established. The physician can charge a high fee for a new procedure and have it reviewed for its reasonableness by a medical review committee composed primarily of practicing physicians. After these fees are established and comparative fee screens are developed, the new procedures remain highly rewarded relative to old procedures.

The Federal Government could adopt for Medicare, Medicaid, and CHAMPUS several options for physician payment to address these problems.

Option 6: Mandate that Federal insurance programs adopt fee schedules that change the relative prices of new v. old procedures and device-bound v. cognitive procedures.

The objective of developing fee schedules that change relative prices is not to discourage the introduction of new devices, but to remove the present financial incentives to select one procedure over another (239).

Implementation of this option would require collection of data on the costs of performing both new and old procedures in order to establish relative prices. It would also require a system for monitoring cost changes in procedures as they diffuse into the practice of medicine (140). Moreover, it is not clear that relative costs are the most appropriate basis for relative prices. Prices should reflect the relative values of procedures, but because of present distortions in the pricing system, it would be difficult to identify differences in these relative values. Hence, setting relative fees would require making judgments about technologies, specialties, and classes of medical care because relative fees affect their use.

How would relative price schedules be affected by voluntary assignment as now exists under Medicare? Voluntary assignment effectively turns a fee schedule into a benefit schedule. A fee schedule limits the amount actually received by the provider, whereas a benefit schedule limits the amount that will be paid by the insurer. Under a fee schedule, the insurer pays only the stated price for a procedure and requires the provider to accept that price as payment in full or not be paid for the service at all. Under Medicaid's mandatory assignment system, a relative price schedule would be a fee schedule. With voluntary assignment, however, the physician could collect the difference between the billed charge and Medicare's payment from the patient, rendering the payment limit a benefit schedule.

To some extent, then, a benefit schedule that paid relatively less for services associated with medical devices and more for cognitive services would result in Medicare patients' paying a greater share of the costs of medical devices. Since people generally use fewer services the greater the level of cost-sharing, the relative use of medical

devices would be expected to fall somewhat, but the extent of this effect is unknown.

Option 7: Mandate that Federal insurance programs pay physicians by episode of illness or by person served rather than by procedures or services delivered.

Just as DRG hospital payments provide incentives for hospitals to treat each hospital case in the least costly manner possible with the least costly mix of devices and other inputs, payment for ambulatory physicians' services by the episode or case would offer similar incentives to physicians. In particular, the financial incentives to provide more laboratory tests and other device-bound procedures than is cost effective would be eliminated.

However, this approach would not only eliminate financial incentives to perform specific procedures, since each procedure performed would reduce physicians' net incomes. Whether physicians would actually respond to those financial incentives is unknown. Underprovision of laboratory and other device-bound procedures would be a possibility in some cases and would require monitoring.

This option would also require development of new systems of classifying patients according to medical conditions, complaints, or health status. Otherwise, people with serious conditions and higher use rates might gravitate to certain providers and overburden them financially ("adverse selection"), or some providers might try to attract people considered less costly to treat ("cream-skimming"). At present, the technology of patient classification does not appear to be well developed in the ambulatory care area.

One way to begin implementing this option would be to focus on physicians' services to hospital inpatients. Physicians could be paid a specific fee based on the patient's diagnostic category for the entire hospital stay, rather than for each inpatient visit. This arrangement would provide financial incentives to reduce the number of physician visits to the hospital and, as a consequence, the number of procedures ordered. However, even this limited use of per-episode physician payment would be difficult to implement soon. First, a

classification system appropriate to physicians' inputs has not been developed, and the validity of DRGs as a classification system for physicians has not been tested; second, physicians' claims data are not organized in a way that readily allows estimation of the relative use of physician service by inpatients in different diagnoses.

The development of adequate patient classification systems to support payment on a basis other than fee-for-services is expensive, and individual payers have little incentive to support such research. As it has in the past, the Federal Government through HCFA could take the lead in supporting research in this area.

Hospital Payment

Medicare's new DRG payment system establishes a different set of incentives for hospitals. These incentives represent an improvement over the previous cost-based reimbursement system because, unlike the old system, they encourage hospitals to treat each inpatient case in the least costly manner possible. Of course, the DRG system is new and hardly complete; further modifications in its administration can be expected. One such modification with particular relevance to medical devices is the treatment of capital costs. The current system leaves capital costs (depreciation and interest¹⁹) reimbursed as they are incurred, with no limit on the amount that a hospital can be paid. In conjunction with fixed payment for most other components of inpatient costs, this approach encourages investment in medical equipment and facilities relative to personnel and supplies, which are controlled.

Option 8: Amend the Social Security Act to include payment for capital in DRG payment rates.

The fundamental issue under the newly created Medicare DRG payment system is whether a hospital's capital payment should or should not be subject to some kind of externally imposed limit. The current passthrough reimbursement of capital could continue as a permanent feature of DRG

payment. Alternative methods of capital payment that impose limits on reimbursement fall into three categories: 1) those that establish uniform rates of payment across all hospitals (or all within a class); 2) those that establish hospital-specific limits to capital payment; and 3) those that condition payment on approval of capital expenditure projects.

The uniform payment approach would treat all hospitals alike, regardless of their capital or operating expenditures. Uniform payment could be calculated either as a fixed percentage of the DRG price or as a flat rate per bed. Hospital-specific approaches, on the other hand, would take the hospital's capital or operating costs into account in establishing a level of payment, but limit increases in the payment level over time. Thus, for example, capital payments could be limited to a percent of operating costs, so that hospitals with high operating costs would receive a higher capital payment than others; alternatively, the capital payment in any year could be tied to the hospital's actual capital costs (as measured by interest and depreciation) in a base year with adjustments for inflation in subsequent years.

If capital payments were controlled through direct regulation of capital expenditures, only projects approved by a certificate of need (CON) or other designated agency would be recognized by Medicare for capital payment. Approved projects would then be paid on a cost basis. Areawide or statewide annual capital expenditure limits could be used to establish an upper bound on the value of approved projects. The State of New York is currently considering adoption of such a capital expenditure limit (38).

The alternative capital payment methods described above can be evaluated on the basis of four general criteria:

- *Efficiency*—the extent to which the approach promotes the cost-effective use of hospital devices.
- *Equity of access to medical technology*—the extent to which the method promotes equal access among population groups to capital-embodied medical technology.
- *Fairness*—the extent to which the method treats all kinds of hospitals alike, neither

¹⁹Capital cost also includes a payment for return on equity, but only to proprietar hospitals.

rewarding nor penalizing hospitals for conditions outside their control.

- Feasibility—the extent to which the method is administratively workable and politically acceptable.

As discussed above, a permanent capital cost passthrough under DRG payment violates the efficiency criterion, because it distorts incentives for hospitals to adopt and use capital-embodied devices. However, this approach does well on the other three criteria. Its feasibility has been demonstrated through the years. It is inherently fair because all hospitals face the same rules regarding capital payment. Finally, it poses no barriers to equal access to medical technology, although it does nothing to redress current inequities.

Any of the three controlled payment methods described are more efficient than passthrough capital payment, because the hospital is encouraged to provide its care at the least possible cost. New medical devices would be judged in terms of their impact on total costs, not just on operating costs. Hospitals would be further encouraged to specialize and join in plans for regionalization of health services. However, it is difficult to devise a controlled payment system that is fair to all hospitals. In a uniform payment system, hospitals that in the past have had lower ratios of capital to operating cost would receive more than they had in the past, while those with high ratios would receive less.

A uniform rate of payment would also create a difficult and possibly costly transition if hospitals that have made major investments in recent years or anticipate them in the near future are not to be unduly penalized. The American Hospital Association has recently proposed a uniform capital payment system that would pay each hospital the higher of cost-based reimbursement or a fixed payment rate during a 10-year phase-in period (8). Anderson and Ginsberg have suggested a less generous transition in which “budget neutrality” is maintained by gradually reducing the proportion of the capital payment that is a pass-through (14).

Tying capital payment to the level of capital costs in a base year or to the hospital’s operating costs is efficient but may be unfair. This kind of

system tends to reward those hospitals who were most capital-intensive in the past, leaving those with low levels of capitalization forever to receive lower payments. Moreover, it would not work well for hospitals requiring major capital expenditures in the early years of implementation. Perhaps for these reasons, support for this approach has been limited to movable equipment, which typically has shorter lifetimes and lower variations in asset values among hospitals.

Hospital capital has two components: the fixed plant and equipment constructed with the facility (new hospital, addition, renovation), and the movable equipment placed in the facility. All capital-embodied medical devices fall into the movable equipment category. The useful lives of movable equipment are usually relatively short (5 to 10 years) and most, but not all, individual equipment purchases are much smaller than the costs of construction. Therefore, it is possible and perhaps even prudent to consider these two classes of capital separately.

Two States, New Jersey and Maryland, have included in their prospective per-case payment systems controls on major movable equipment expenditures (345). In the case of Maryland, the hospital’s current value of undepreciated equipment in a base year is built into the controlled hospital rates, with adjustments only for inflation in subsequent years.²⁰ In New Jersey, the amount allowed for major movable equipment is determined by a blend of the hospital’s own current value of undepreciated equipment and the average current value of undepreciated equipment in similar hospitals in the State.

Inclusion of major medical equipment in the DRG payment prices would encourage hospitals to consider the cost of such equipment in decisions about the most appropriate mix of resources. It would probably require a transition phase for new (and newly equipped) hospitals, but the length of the transition could be short due to the short useful lives of the equipment in this category.

²⁰Exceptions can be negotiated with the State’s Health Services Cost Review Commission.

It is difficult to predict the effects of direct regulation of capital expenditures through CON or other agencies. Direct regulation can occur with or without statewide or areawide maximum limits on total capital outlays over a given period, and the effects can be expected to differ between the two. Although there has been much discussion in certain States about establishing actual expenditure limits or “pooling” capital, all experience to date has been with CON and section 1122 programs that do not operate with areawide or statewide limits. The experience with capital expenditures regulation in the absence of such limits has been disappointing, with most evaluations concluding that the level of capital expenditures has not been affected (61,63,247,436). Moreover, the distribution of medical technologies among hospitals does not appear to have improved as a result of CON (61).

There is no evidence, either theoretical or empirical, to suggest that the outcome of an annual limit on the level of capital expenditure process would be either efficient or fair (447). A review of the literature on resource allocation decisions by committees revealed that the ultimate outcomes depend on chance and on the composition of the committee and the procedures governing the decisionmaking process (447). Moreover, the kinds of information needed to make informed tradeoffs among competing capital projects is likely to be unavailable, thus leaving the process even more exposed to political solutions.

Regardless of whether or not an areawide limit is applied, direct regulation of capital expenditures is administratively feasible only for large projects —construction and renovation projects and major new services. The current trend toward high thresholds for capital expenditure controls (453) would probably continue, leaving an ever larger proportion of capital-embodied technology to be controlled in some other way.

Systemwide Reforms

All of the options discussed above involve specific adjustments to a payment system that has two fundamental problems: first, the more units of service that are offered, the more the Provider

is paid, resulting in greater use of the medical services, including devices; and second, the more restrictive one part of the payment system becomes relative to others, the greater is the incentive to shift the settings of service delivery from the more restrictive to the less restrictive ones.

When financial incentives are inconsistent with cost-effective adoption and use, regulatory approaches can be attempted, but they are often unwieldy. For example, the regulatory process of coverage for medical devices creates differential barriers to the introduction of new devices that have little to do with their effectiveness or cost effectiveness. Despite this fact, the sheer size of the task of individually reviewing each medical device for its efficacy and safety (not to mention cost effectiveness) in each potential use as a precondition to coverage argues against the development of such a coverage process. Instead, the difficulties inherent in the coverage process outlined in this chapter seem to support the development of payment methods that create incentives for individual providers or users to make decisions that are consistent with the goals of the Medicare program.

Option 9: Encourage Medicare to move toward payment for medical care (including devices) on a per capita basis.

One remedy for the problems of the current system may be the adoption of per capita payment, in which a set of defined and reasonably comprehensive services is offered in exchange for a fixed premium. Under per capita arrangements, such as those offered by HMOs, all resources used to produce health services are subject to the same constraints, and incentives exist to select the least costly mix of resources.

Per capita payment has two potential problems, however, which suggest that careful assessment be given to this alternative. First, there is the possibility under these plans that people with the greatest need or demand for medical care will enter specific plans and that other plans will selectively enroll low users, leading to unequal cost burdens among alternative plans. Varying the amount of the payment by the age or existing health status of the beneficiary would address this

problem, but it is difficult to identify factors that will be associated with greater medical care need. Second, just as fee-for-service medicine gives providers an incentive to provide too many services, providers of services on a per capita basis would

have a financial incentive to provide too few. However, competition among plans and the costs of malpractice insurance may limit this risk of underprovision.