

Chapter 7

PAYING FOR HOME DRUG INFUSION THERAPY UNDER MEDICARE

Contents

	<i>Page</i>
Overview	133
Introduction	133
Summary of Conclusions	133
Potential Payment Methods	134
Background ..*.*.*.*.*. ... o..*.*.*.*.*. *o*.*.*do.....**...**..	134
Existing Methods of Paying for Drug Infusion Under Medicare	135
Examples of Potential Payment Models for HDIT	138
Goals and Tradeoffs	141
Access	142
Quality Assurance	143
Equity	144
Cost Control	144
Administrative Feasibility	145
Evaluating Payment Alternatives	146
Retrospective Charge- or Cost-Based Reimbursement	146
Competitive Payment Methods	147
Noncompetitive Prospectively Set Rates	147
Other Issues	148
Paying for Drug Infusion Therapy in Skilled Nursing Facilities	148
Physician Compensation and Ownership	149

Box

<i>Box</i>	<i>Page</i>
7-A. HDIT Under Prospective Per Capita Payment	141

Tables

<i>Table</i>	<i>Page</i>
7-1. Medicare Payment Methods for Durable Medical Equipment	137
7-2. Example of One Insurer's Prospective Per-Diem Fee Schedule	140
7-3. Presumed Quality Incentives Under Alternative Payment Methods	143

PAYING FOR HOME DRUG INFUSION THERAPY UNDER MEDICARE

Overview

introduction

The sheer size of Medicare as a purchaser of health care means that the consequences of its payment decisions will permeate every aspect of home drug infusion therapy (HDIT). How the service is reimbursed will affect the willingness of providers to offer it, the willingness of physicians and patients to use it, the content of the care provided, the setting in which it is offered, the future structure of the industry, Medicare expenditures, and, ultimately, health care system costs. The purpose of this chapter is to briefly describe the different methods of payment that are possible and discuss their potential implications if applied to HDIT.

Summary of Conclusions

- There is no single obviously best method by which to pay for HDIT. Three methods, all of which are currently in use in some form, could be implemented almost immediately: cost-/charge-based reimbursement (amplifying on existing Medicare home benefits and payment methods); all-cost-based reimbursement; and prospective, government-set rates per item, per diem, or possibly per episode of infusion. Two other possibilities—competitively set rates and bundling home infusion into hospital inpatient rates—could be implemented but involve much greater administrative effort or would require much more information before implementation.
- Of the three payment methods that could be implemented immediately, cost-/charge-based reimbursement would be the simplest to implement but offers strong incentives to overprovide care and the fewest possibilities for cost control. All-cost-based reimbursement offers incentives to provide high-quality, accessible care to Medicare beneficiaries, but it also encourages the provision of costly services and may be somewhat inflationary. (Placing a cap on allowable costs might reduce cost increases to some extent.) Prospectively set rates offer the greatest possibility for cost control. Prospective rates for HDIT have been used successfully by private insurers, and more information is available to set rates than was true at the time the Medicare Catastrophic Coverage Act (MCCA) was passed. However, this method could endanger patient access and quality of care if rates were low and quality of care could not be monitored adequately.
- If prospectively set rates are chosen as the method of payment for HDIT, bundling at least nursing and pharmacy services, supplies, and equipment into a single rate (or set of rates) might reduce paperwork burdens and system “gaming.” Continual advances in new technology and potential tradeoffs between nursing needs and equipment costs for some technologies means that, if payment were according to an itemized fee schedule, Medicare might find it difficult to keep up with changes in the therapy and still keep costs under control.
- Some private insurers have successfully implemented HDIT “preferred provider” programs, under which providers agree to meet quality standards and accept the insurer’s payment rate as payment in full, in exchange for the likelihood that more of that insurer’s patients will use the provider’s services. A similar program requiring mandatory assignment for HDIT providers serving Medicare patients would reduce patients’ risk of being billed for charges in excess of the Medicare payment rate. A lack of providers willing to participate would be one indicator that Medicare payment rates were set too low.
- Good-quality HDIT requires intimate physician involvement. Paying physicians for this involvement would enhance quality of care and remove existing physician incentives to either avoid HDIT or receive “consulting fees” and other remuneration from HDIT providers. To control costs and prevent physician “unbundling” of services for billing purposes, Medicare could pay a single rate for physician services related to a single specified period of time (e.g., per day, per week, or per episode of infusion therapy). Separate provisions could be made for patients on indefinite or multiple therapies.

- Many patients who could be served with HDIT might be equally well or better served by infusion therapy provided in a skilled nursing facility (SNF) or an outpatient facility. Payment for infusion therapy in these settings deserves study and possible revision concomitantly with consideration of payment for HDIT. In particular, higher payment for infusion provided in SNFs may be warranted where it can be provided with good quality in this setting. Similarly, rural swing-bed patients on drug infusion therapy should receive adequate reimbursement, particularly when the hospitals are unable to discharge patients due to a lack of qualified HDIT providers.
- Physician ownership of drug infusion facilities presents some troubling issues. Physicians are the critical source of referrals for HDIT providers, and physician ownership of a provider may inhibit referrals to other providers even if those providers offer care of equally high quality and lower cost. For some physicians, office-based infusion-in which the actual drug infusion is performed in the physician's office-is a direct extension of the physician's usual practice. Although this also represents a "captured" referral, it raises slightly different issues than physician co-ownership of other outpatient and home infusion companies.

Potential Payment Methods

Background

Two basic payment methods are used to pay for health care services: *retrospective* methods, in which the amount of payment is determined after the services have been provided; and *prospective* methods, in which the rate is set before the visitor service actually takes place.

Retrospective Methods

Retrospective cost- and charge-based payment methods were the original mainstays of Medicare payment to health care providers. Hospitals, for example, were originally reimbursed based on their actual allowable costs of serving Medicare patients (359). Most home health services continue to be reimbursed by Medicare in this way (although there are limits on the amount paid). Charges (rather than

costs) were the historical basis for paying physicians and for reimbursing for such items as laboratory tests and home durable medical equipment (DME) (359, 360).

Retrospective cost-based payment creates some strong financial incentives for providers. First, since such methods usually allow for recovery of full average costs, including a return on capital investment, providers with marginal costs that are lower than average costs make a profit on each service provided.¹ Thus, they have an incentive to serve as many patients as possible. Second, for each individual patient, providers have an incentive to offer as many services as possible (including services that provide little real benefit to the patient). Third, there is little incentive for providers to produce services efficiently, since they can recover any expenses related to production. And fourth, where cost-based payment exists side-by-side with other payment methods, providers are encouraged to use whatever accounting flexibility they have available to attribute costs to the cost-reimbursed service.

Cost-based payment can lead to poor-quality care if unneeded services (with their attendant risks, however minor) are provided. However, it can also lead to high-quality care if providers choose to compete on the basis of quality (since competing on the basis of cost confers no advantage under this method).

Where actual costs are difficult to determine, historically Medicare has paid on the basis of charges. Like cost-based payment, retrospective charge-based payment contains incentives to increase the number of services as long as the charges for the service are higher than the costs of providing the service (as, presumably, they usually are). And, like costs, charges as the basis of payment tend to be inherently inflationary, since there are few incentives for providers to reduce them. Because charges are limited only by the competitiveness of the marketplace and what providers deem appropriate to bill, Medicare now pays for few services at their actual or average charge. However, many items and services are currently reimbursed at set rates according to a fee schedule, and the level of (and variation among) rates can often be traced to the average charges that served as the original basis for the fee schedule.

¹ See p. 196 for definitions and a discussion of marginal and average costs.

Prospective Methods

In contrast to retrospective methods, prospective payment involves determining payment rates in advance of service delivery. Because payment is unchanged by the actual costs of producing that particular service, providers have an incentive to reduce costs. Providers may also have an incentive to reduce service quality as a way to reduce costs unless there are counterbalancing forces (e.g., competition for referrals or regulatory penalties). Thus, use of such methods may require enhanced levels of quality monitoring and assurance. Difficulties in updating prospective rates can also present problems. Fixed-rate schedules may be less responsive than competitive approaches to changes overtime in technology and production processes.

The effect of a given prospectively fixed rate schedule depends on such factors as the level of the rates and the base units to which the rates apply. Very high rates encourage inefficient production of services; very low rates may discourage providers from participating in Medicare or offering the service at all. Rates applied to a very detailed level of service (e.g., a single visitor piece of equipment) may offer different incentives to under- or overprovide these services than rates that apply to a bundle of services (e.g., all services provided on a given day).

Prospective rates may be freed in advance by the payer and applied equally to all providers with little direct provider input (e.g., fee schedules determined by past charges). Alternatively, they can be set through competitive bidding or negotiation with providers. For example, the payer may advertise a contract for providing a certain service to patients and contract with the provider(s) offering the lowest price for that service. Or, the payer may enter into direct negotiations with providers, with different providers receiving different rates. Such payment methods have been employed by the Department of Veterans Affairs and some Medicaid programs for purchasing home oxygen and other home medical equipment items (82).

These options avoid some of the difficulty the payer may otherwise face in determining what an appropriate rate should be, since in this case market forces determine the payment rate. In order for a competitive bidding-based system to be effective, however, there must be sufficient market competition to ensure that all the bids will not be artificially

high. The service must also be sufficiently well-defined to enable it to be specified exactly in the contract or negotiation process.

Establishing market-based prospective rates may be a time-consuming and expensive process, particularly if it requires individual negotiation with many providers. In addition, this method raises the same need for quality assurance activities as other prospective fixed-rate methods.

Existing Methods of Paying for Drug Infusion Under Medicare

Hospital Inpatient Infusion

Drug infusion therapy provided to hospital inpatients is reimbursed through Medicare's hospital prospective payment system, in which rates for the coming year are set prospectively for each diagnosis-related group (DRG). Hospitals do not receive payment specifically for the infusion supplies and services or associated laboratory tests. Rather, those costs are lumped with all other costs of treating patients in each DRG, and the payment for that DRG is assumed to cover the average costs of all patients it comprises. Hospitals that can reduce the costs of treating any one individual (e.g., by using a less expensive drug, reducing the nursing visits necessary, or discharging a patient early) will maximize their profit (or minimize their loss) on that individual.

In certain DRGs (e.g., the one that includes osteomyelitis), patients receiving long-term drug infusion make up a substantial proportion of all patients (285). The costs of infusion therapy in these DRGs is thus a significant proportion of total costs, and changes in the amount of inpatient infusion would have a major effect on the future reimbursement for all patients in these DRGs. In contrast, in DRGs for which drug infusion is an infrequent treatment, or limited to patients with very short-term needs, discharging patients who are on long-term infusion would have little effect on future inpatient payment rates.

Nonetheless, because hospitals receive the same per-patient payment regardless of whether the patient is discharged early or remains in the hospital, hospitals have a strong incentive to transfer long-term infusion patients to other settings as rapidly as possible. This incentive is unchanged by future lower payment rates in high-infusion DRGs; hospi-

tals still reduce their costs by discharging infusion patients as early as they can.

Infusion in Other Facilities

Outpatient Facilities--Medicare payment for outpatient drug infusion depends on the setting in which it takes place. If the setting is a hospital outpatient department, infusion is reimbursed retrospectively on a cost basis (i.e., based on Medicare's share of hospital costs actually incurred) for drugs, services, and most supplies and equipment. If the setting is a physician's office, reimbursement is retrospective and based on the physician's charges, within the limits of what Medicare allows. (Beginning in 1992, Medicare is phasing a fee schedule for physician services, but it is not yet clear how this will affect office-based infusion services.) In both cases, providing more infusion results in more reimbursement to the facility (or physician).

Skilled Nursing Facilities--Drug infusion in SNFs is covered under the usual prospectively set daily SNF rate and paid under Medicare Part A. Hence, these facilities incur costs but receive no more reimbursement in the short run when infusion therapy is provided. (In the long run, as with hospitals, incurring infusion costs in one year may raise reimbursements in future years, but the return is not directly related to the service provision for that individual patient.)

Ancillary Services--For all nonhospital infusion, related laboratory tests are reimbursed separately. Medicare pays the clinical laboratory directly on the basis of a fee schedule that is limited by a national cap on maximum fees for specific services. Medicare pays a separate nominal fee (up to \$5) to cover the costs of specimen collection when skilled personnel are necessary (e.g., to perform a venipuncture). For beneficiaries who are homebound or who are inpatients of a nonhospital inpatient facility, Medicare also pays the transportation costs of skilled personnel who travel to the patient's residence to collect such specimens (SSA sec. 1833(h)).

Home Infusion

In the home, unlike other settings, the supplies and services that make up drug infusion therapy are generally reimbursed independently in different ways. In addition, drugs are only occasionally directly reimbursed by Medicare. (Physician services and laboratory tests are separately reimbursed, as they would be for any other nonhospital service.)

Equipment--Medicare payment for medical equipment (e.g., infusion pumps, IV poles) and related supplies under the Part B DME benefit is retrospective, based on the lower of the actual charge or a local fee schedule amount (SSA sec. 1834). A separate fee schedule is established for each of six categories of DME (table 7-1).

Fee schedule amounts were initially determined by carriers (the Part B fiscal intermediaries, or FIs) based on local charges for the equipment and have been updated by inflation. The Omnibus Budget Reconciliation Act of 1990 (Public Law 101-509) mandated a transition to a national rather than local fee schedules for DME, to be fully implemented by 1993.

Home Health Services--Services provided by a home health agency (ID-IA) are reimbursed on the basis of retrospective costs. The computed reasonable cost per visit is subject to nationally applied limits for each type of service² for freestanding HHAs.³ Hospital-based HHAs are permitted higher limits to account for presumed higher administrative and general costs.

For the purposes of reimbursement, the provision of any of the covered home health services by a particular skilled nurse, skilled therapist, or home health aide on a particular day or at a particular time of day is considered a visit. For example, a registered nurse and a physical therapist providing services on the same day would be considered two visits. Two separate visits by a nurse on the same day would also be considered two visits, but if a nurse performs two separate services during the same visit (e.g., skilled nursing services and home health aide services) it is covered only as a single visit.

²IjqMs of services are skilled nursing care, physical therapy, speech pathology, occupational therapy, medical social services, and home health aide services.

³Although calculated by service, limits are actually applied in the aggregate, permitting HHAs to offset high-cost services with low-cost services (353). A recent study by the General Accounting Office concluded that cost savings are greater when limits are applied by type of visit rather than in the aggregate, and that the impact on beneficiary access and quality of care would be minimal if HCFA applied limits by type of visit (353).

Table 7-I—Medicare Payment Methods for Durable Medical Equipment (DME)

Category	Payment method
Inexpensive rental payments or routinely purchased DME	Lump-sum purchase amount or monthly rental payments whose total may not exceed the lump-sum amount.
Items requiring frequent or substantial servicing	Monthly rental until the period of medical necessity ends.
Customized items adapted for a particular patient	Lump-sum purchase amount determined by the carrier with consideration as to the equipment’s maintenance and servicing needs.
Prosthetic and orthotic devices.	Lump-sum purchase amount for most prosthetic and orthotic devices. Intraocular lenses; parenteral and enteral nutrition nutrients, supplies, and equipment; and prosthetic devices that fall into other Medicare coverage categories (e.g., artificial limbs) are exceptions that are subject to different rules.
Capped rental items	Monthly rental amount that is at the lesser of the actual charge or 10 percent of the fee schedule amount for the equipment. Payment may not exceed 15 continuous months of equipment rental. Suppliers must continue supplying rented DME at no additional charge to the beneficiary after Medicare payments have stopped, provided that such rental continues to be medically necessary. Maintenance and servicing fees are calculated separately on a reasonable charge basis for each item.
Oxygen and oxygen equipment	Monthly rental according to a fee schedule specific to the type of equipment.

SOURCE: Office of Technology Assessment. Information from Social Security Act, section 1324 (a).

Drugs-Drugs are rarely explicitly covered in the home. The single exception is for certain drugs that are covered under the DME benefit (as part of an infusion pump; see ch. 6). In these cases, Medicare usually pays for the drug based on either historical charges for that drug code for a given carrier or the listed average wholesale price (AWP) of the drug. Occasionally, the drug is simply included in the payment for the infusion pump (365).

With exception of DME-based payment, payment for the drug to be infused must come either directly from the patient, from the providing pharmacy (as charity care), or from another interested provider. Specifically, a hospital may choose to pay for the drug (or donate the drug) in order to discharge a Medicare patient from the hospital and reduce inpatient costs while retaining the full inpatient payment. Anecdotal accounts of this practice are widespread, but there are no data on the frequency with which it occurs.

Hospice Services

Medicare pays for hospice-related infusion services under the prospective fee schedule for hospice services. Each day of hospice care is classified into

one of four ‘levels of care.’ Medicare pays hospice programs at a per diem or an hourly rate, depending on the level of care to which that day is assigned. Including infusion services does not change the daily payment. The four levels of care are:

- *routine (periodic) home care;*
- *continuous home care (at least 8 hours of home hospice care per day);*
- *general inpatient care (for symptom management or pain control that cannot be provided in the home setting); and*
- *inpatient respite care for up to 5 days (to provide respite for family caregivers) (74).*

Payment for all hospice services is subject to a cap on total payment per patient (74). The only covered services not included in the prospective rates are the direct patient care services of physicians. For physicians employed or paid by the hospice, direct patient care services are reimbursed on the basis of charges for those services. The services of other physicians are paid through Part B in the same way as nonhospice physician services.⁴

⁴ Payments to hospice physicians are made in addition to the daily rates but are counted toward the overall cap on per patient hospice payment. Part B payment for physician services is not counted toward the overall cap (74).

Examples of Potential Payment Models for HDIT

Unbundled Retrospective Payment: The Existing Medicare Home Benefit Model

Medicare's existing payment methods for home nursing and equipment offer the most basic model for an HDIT payment method. Under this model, the different components of HDIT would be paid separately in the same way they are under existing benefits. Equipment and supplies would be reimbursed according to the present method of paying for DME and related supplies; payment could be made either to an HHA or directly to the DME supplier. Infusion-related nursing services would be paid on the basis of visit costs under the HHA methodology. Physician services and laboratory services would be reimbursed in the same manner as at present.

Drug payment has less precedent under the current system. Most carriers pay based on their own charge experience, but the drug codes in the Medicare coding system are crude and often inadequate (365). Pharmacy services are not explicitly recognized.

At present, the only well-developed payment model for home-infused products and related pharmacy services is the existing method of paying for home total parenteral nutrition (TPN).⁵ Under the Part B prosthetic device benefit, payment for nutrients administered in the patient's home is based on the reasonable charge for the various solution components provided to the patient (379). The charge for the nutrients implicitly includes payment for related pharmacy services, since these services are not recognized separately. All TPN bills are processed and paid by two regional carriers to ensure consistency in coverage and payment policies. At the least, extending the TPN payment model (or almost any other payment model) to drugs requires the development of much more detailed drug codes.

Prospective Payment for Bundled Services: The ESRD Model

Like drug infusion therapy, dialysis for patients with end-stage renal disease (ESRD) can be provided at home and involves a sophisticated mix of medical equipment, supplies, and services. Existing

payment methods for chronic dialysis thus are potentially applicable to HDIT as well.

Medicare pays for medical care associated with home dialysis in one of two ways:

- *Method 1*—If a home dialysis patient receives care from an approved dialysis facility, Medicare pays that facility a monthly rate that includes all services, supplies, equipment, and certain laboratory tests associated with dialysis. Separate monthly rates apply to continuous cycling peritoneal dialysis and intermittent dialysis (379). Claims are processed by the Medicare Part A intermediary.
- *Method 2*—If a home dialysis patient obtains supplies, equipment, and services directly from the supplier, Medicare pays the beneficiary (or the supplier) its share of the reasonable cost of these items. Payment is per item, but total monthly payments for all items may not exceed the applicable composite rates under method 1 (Public Law 100-239). Claims are processed by the Medicare Part B carrier.

The vast majority of Medicare home dialysis patients are covered under the method 1 composite rate (74). The new cap on method 2 payments has been difficult to implement in some areas because supplies are not billed locally (e.g., a patient on home dialysis in South Carolina may receive equipment from a supplier in Georgia) (45).

Laboratory tests not included in the method 1 composite rate are paid as any other Part B diagnostic laboratory services under fee schedule for those services (379).

All physician's services that are related to the continued management of a home dialysis patient are reimbursed by the carrier under a separate monthly cavitation payment (MCP). The amount of the MCP is based on local prevailing charges for medical specialists' followup office visits in 1981, as periodically updated since. In 1988, the MCP for any given locality was subject to a minimum of \$132 and a maximum of \$203. Services unrelated to dialysis management may be billed separately from the MCP. Payment for self-dialysis training services provided by a physician is also made separately from

⁵There is currently no written policy for TPN payment, although the carriers have special instructions from the Health Care Financing Administration (HCFA). The Office of Technology Assessment (OTA) obtained information about coverage and payment directly from HCFA's Bureau of Program operations.

the MCP amount (at a flat rate of \$500 per patient) (379).

Were infusion drug therapy to be paid according to the ESRD model, reimbursement would be made at one or more flat rates per patient, with the rates including equipment, supplies, and services. The drugs themselves could be either included or excluded in the composite rate, as could laboratory and physician services. The ESRD program also provides a possible model for paying for infusion-related physician services.

Prospective Rates With Participation: The Blue Cross/Blue Shield Model

A number of private insurance companies have instituted HDIT benefits (55), and models from these companies may be applicable to Medicare. Some insurers have instituted benefits paid in a manner similar to the “existing home benefit” model described above; each component is paid based on costs or charges according to preexisting benefit policies (55). Other insurers, however, report satisfaction with a payment model that combines a prospectively set per-service or per-diem rate with a process under which eligible providers agree to become preferred providers if they accept that rate.

In the preferred provider model (used by at least three Blue Cross/Blue Shield plans), the insurer defines some provider conditions of participation and offers a set of rates for a defined set of HDIT services. Area providers that meet the conditions of participation can agree to serve the insurer’s patients at the set rates. In doing so, they agree to “accept assignment” and accept the rate as payment in full. Providers who agree to participate are “preferred providers” in the program; physicians are encouraged to refer patients to them, and patients are encouraged to use them to avoid extra billing. Nonparticipating providers may also serve patients, but they are paid only the set rate and the patient is liable for any additional billed amount (43,243).

To be successful, the preferred provider model for HDIT requires four elements:

- a well-defined set of services to be provided,
- minimum quality standards for chosen providers,
- a rate that is high enough to cover necessary provider costs but lower than at least some billed charges on the market, and

• enough providers in the market to invite competition for patients.

The rate is especially critical. If it is too high, the payer loses the advantage of market leverage and makes unnecessary payments. If the rate is too low, providers will be unwilling to participate because they cannot cover their costs; too few providers mean impaired access for patients.

Two insurers in Arizona and Washington, DC that use this model set rates and pay in slightly different ways. In Washington, DC, infused drugs are paid at a set amount over the listed AWP, based on pharmacist input regarding the preparation time needed for different drugs (43). Equipment is paid according to a rental fee schedule. All other supplies and services (except laboratory and physician services) are “bundled” and paid at a daily rate that varies depending on the amount of nursing services needed that day (table 7-2). The daily rates were calculated from an amalgam of historical charges, manufacturers’ list prices, and professional input (43).

In Arizona, in contrast, rates are established separately for each individual item, whether it be equipment, supplies, or services. Drugs are paid at AWP plus an administrative markup; pharmacy services are paid per dose, based on judgments of a pharmacist panel (243).

Both of these insurers report lower costs than before instituting their respective programs, when they were paying much higher billed charges. Both also report substantial participation rates among area providers, at least in the brief time they have operated thus far (43,243).

The Medicare Catastrophic Coverage Act Model

After the MCCA was passed, the Health Care Financing Administration (HCFA) published proposed regulations that outlined in detail how the home intravenous (IV) drug therapy benefit under that act was to be paid (see app. C for a summary of the proposed regulations). Although they were never made final due to the repeal of the act, these proposed regulations offer a detailed potential model for any future similar benefit. In them, HCFA proposed to pay for home IV drug therapy in two parts: 1) the drugs, and 2) all other supplies, equipment, and administrative, pharmacy, and nursing services.

Table 7-2—Example of One Insurer's Prospective Per-Diem Fee Schedule^a

Description	Payment per day
Medical supplies^b and nursing services	
Initial home nursing visit for instruction and assessment	\$200.00
Supplies only (no professional nursing intervention); patient is self-administering medication.	35.00
Supplies and brief (0 to 1 hour) professional nursing intervention	110.00
Supplies and intermediate (more than 1 to 2 hours) professional nursing intervention	160.00
Supplies and comprehensive professional nursing intervention (more than 2 hours)	345.00
Additional medical supplies for multiple therapies (billed in addition to one of above services)	25.00
Noninfusion maintenance of central line catheter (implantable device)	30.00
Noninfusion maintenance of central line catheter (nonimplantable device)	5.00
Blood transfusion and associated nursing visits (per episode)	475.00
Equipment rental	
IV pole	1.00
External ambulatory infusion pump and administration equipment.	19.00
Stationary infusion pump	12.00
Patient-controlled analgesia infusion pump	16.00
Elastomeric infuser	30.00

^aThis table represents only part of the fee schedule. It does not include items on the fee schedule that relate to nutritional therapy, aerosolized therapy, or other services.

^bF., assumes supplies are distributed by the home care provider.

SOURCE: L. Bodenheimer, Blue Cross and Blue Shield of the National Capital Area, Washington, DC, personal communication, June 28, 1991.

The drugs themselves were to be subject to a payment rate that depended on the exact drug and dosage. The rate for a given drug was the lesser of the actual charge or the calculated payment limit. The payment limit, in turn, was based on a per-dose average price for the drug, derived from published AWP's or HCFA-conducted surveys of drug prices. The payment limit also included a small administrative allowance for each dose (54 F.R. 37208).

All other supplies, equipment, and services were to be included in two per diem rates, one for each general type of covered therapy (i.e., antibiotics and analgesics). Rates were built up through estimates of the cost of providing each of the components of the pharmacy and nursing services and supplies required. Establishing these rates required not only information on per-unit costs but on assumptions

regarding the services required. A patient on antibiotic therapy, for example, was assumed (on average) to require a nursing visit and associated catheter supplies every 3 days, drug delivery every 5 days, and self-administration of one dose (with associated per-dose pharmacy preparation time) 2.5 times each day. Only 10 percent of antibiotic patients were assumed to require pumps (54 F.R. 46938).

The proposed basic fee for pain management therapy (not including the drug) was \$31.63 per day, and the basic daily fee for antibiotic drug therapy was to be \$45.44. These amounts would be adjusted for geographic variation in a wage index and would be reviewed for updating overtime (54 F.R. 46938). In addition, providers would receive one-time or patient-specific allowances for initial patient education and treatment and for patients on multiple drug regimens. Physician and laboratory services were outside the fee schedule and would be paid as any other such services.

Bundling With Hospital Services: A Hypothetical Model

Linking post-hospital and hospital treatments into a single payment for all nonphysician services has never been implemented under the Medicare program, but the idea is not entirely new. In fact, combining hospital and post-hospital home health services was one of the potential payment methods that HCFA considered testing in a demonstration project in the 1980s (381).

In the context of HDIT, bundling with hospital inpatient payment could take two forms. First, the costs of paying for HDIT could actually be included in the prospective payment rate to hospitals for relevant DRGs. In essence, the costs of post-hospital infusion therapy would become for Medicare purposes part of hospital costs, and the calculations of DRG payment rates would simply be adjusted to account for them. All hospitals would receive the new DRG rate, regardless of their actual institution-specific patient experience.

Alternatively, all hospitals could receive the basic DRG payment (which might be lower than at present), and hospitals would receive an additional add-on payment for each patient discharged to HDIT. The add-on would be assumed to cover all costs of the home therapy (except physician services).

In either case, the essential feature is that the hospital receives the payment for the home therapy. Thus, the hospital must either provide the therapy itself (e.g., through its own HDIT service), or pay in turn the outside provider who does so. Bundling HDIT and hospital payment would have the great advantages of reducing hospital incentives for overly early discharge of patients requiring detailed care, while encouraging hospitals to use the most cost-effective setting for patients appropriately discharged to nonhospital infusion. There would be strong incentives to control costs, including limiting the duration of treatment, as payment would essentially be on a per-episode basis.

However, this method would also face substantial implementation difficulties. To correctly update the hospital payment rate, or calculate the add-on rate, the average costs of home infusion patients associated with each DRG would have to be determined. Doing so would be very difficult, since outside providers have little incentive to make their per-DRG costs known even if they know them themselves. Also, this payment method requires that hospitals have sophisticated and ongoing relationships with outside home providers, which would take some time to develop. Fewer than 20 percent of current HDIT providers are hospitals (193). Hospitals unable to provide such services directly would need to solicit bids for such services, much as would be the case with a public-sector agency responsible for a competitive-bidding-based payment system.

Furthermore, a significant and probably increasing proportion of HDIT patients are not hospital inpatients at the time they begin therapy. Individual HDIT providers report that anywhere between 0 and 23 percent of their patients begin their home infusions in outpatient settings (195,250,332), and one provider reports that the proportion increased from 0 in 1986 to 20 percent in 1989 (83). Separate payment methods would still be required for these patients.

Another “bundled service” model would be to pay for all HDIT services through HHAs. Under this model, an HHA providing home health services to a Medicare patient who also required HDIT would receive an add-on for supplies and services directly related to the infusion. Services and supplies by patients needing only infusion, and no other, home health services would be paid to the HHA at some prospective rate slightly higher than the add-on rate.

Box 7-A—HDIT Under Prospective Per Capita Payment

The most comprehensive “bundle” of services to which a prospective rate may be applied is the universe of health care services an individual needs during a given time period—“per capita” payment. Here, a provider receives a predetermined fee per year for every beneficiary enrolled with that provider, regardless of whether the beneficiary actually uses any services. Payment includes not only infusion therapy but all other acute and primary care (and, sometimes, some long-term care as well).

This model is already in place for Medicare beneficiaries enrolled in health maintenance organizations (HMOs), which receive a capitated rate that includes all the Medicare benefits to which a patient is entitled. In essence, for HMOs, payment for HDIT is “bundled” with payment for all other health care services.

Some HMOs provide HDIT themselves for those beneficiaries they deem eligible (389); others contract with outside providers who offer the service. The outside providers, in turn, may accept either fees-for-service or a capitated rate for the patient pool, with the exact number of patients they will serve unknown at the time the rate is set (186). In contrast to per capita payment for all basic health services, there is very little experience yet with per capita payment to HDIT providers to cover only this therapy.

The advantages of this model relate less to cost-effectiveness incentives than to care coordination incentives; patients needing both infusion and other home health services would have care coordinated within a single provider. Like the hospital bundling model, this model has the disadvantage that it requires agencies that do not provide infusion in-house to have arrangements with other providers. This disadvantage is not be trivial; at present, it appears that many HHAs have little direct experience with HDIT.

Goals and Tradeoffs

Any payment method is a compromise to achieve the best result given a number of competing goals. Among the major goals of the Medicare system are:

- *Access* to necessary medical care for Medicare beneficiaries. This goal can be achieved only if payments to providers are adequate to induce

sufficient supply to serve Medicare beneficiaries.

Care of acceptable quality for beneficiaries. To ensure care of at least minimum quality, Medicare may provide incentives for providers to produce care of high quality (e.g., by giving higher payments or conferring a market advantage to high-quality providers). Alternatively, Medicare may implement quality monitoring and assurance systems, under which payment is denied when certain indicators fall below acceptable standards.

- *Equitable treatment* of beneficiaries, providers, and other participants in the health care system. For beneficiaries, the goal is equity of access and cost burdens; for providers, the goal is fair payment and participation rules.
- *Cost controls* that keep program, beneficiary, and health system costs as low as possible. Because cost control competes directly with other objectives, payment systems are usually designed to achieve appropriate levels of cost, consistent with other goals, rather than to achieve the minimum possible costs.
- *An administratively feasible program* that can be implemented. To be successful a payment method must be workable for both government administrators and for providers. Some programs may be very complex and costly to administer; for others, the information base needed to implement the program (e.g., to determine appropriate payment rates) may be lacking. Programs may also differ in their acceptability to providers and the costs of overcoming poor provider participation.

These policy goals are not entirely distinct from one another. Administrative feasibility, for example, could be considered a subset of program costs. Focusing on each separately, however, highlights the tradeoffs between goals that are inherent to the different basic payment methods.

Access

Access to care for beneficiaries requires providers who are willing and able to provide care. Sometimes, access is endangered because no providers exist—for example, in a rural area with insufficient population density to support a home infusion provider. In other cases, providers may exist but may

be unwilling to serve Medicare patients. Because willingness to serve patients is often related to reimbursement for services, Medicare must trade off the desire for program cost control with the need to ensure the participation of adequate numbers of providers in every service area.

For Medicare home health services, which are reimbursed on a cost basis, provider participation has not been a problem. Nonetheless, provider participation could become an important issue if Medicare adopted a fee schedule that providers found inadequate. It has been documented that physician participation in the Medicaid program is directly related to rates paid (143,152,313). In some areas, physician willingness to accept assignment (which implies acceptance of Medicare's payment rate) for Medicare patients has also been an issue (56,180,214). The consensus of research in the past has been that an increase in payment rates (relative to physician charges) would increase physician willingness to accept Medicare assignment (56, 221,255).

If providers cannot control the payment they receive for services, they can still to some degree control the types of patients they serve. Nursing homes, for example, have been thought to select patients requiring the least costly care in order to maximize profits under a fixed-rate payment system (173). HHAs, currently reimbursed for their costs, have little reason to be selective in serving patients (though they may try to avoid or terminate particularly troublesome patients who exact an emotional cost on staff that is not reimbursable). A freed-rate payment scheme, however, could create incentives for HHAs to find ways to serve the less costly patients. This might be accomplished through establishing outreach and referral networks directed toward low-cost patients, or by encouraging the transfer of costly patients to other providers.

The payment rate necessary to induce a sufficient number of providers to offer their services to Medicare patients may vary among geographic locations and according to local market conditions. If access is to be ensured for all, it may be necessary to tailor rates to market area characteristics. Or, if uniform rates were to be used, Medicare could allow rates that are higher than necessary in low-cost areas to ensure adequate supply in high-cost areas.

Table 7-3-Presumed Quality Incentives Under Alternative Payment Methods (relative to cost-based reimbursement)

Payment method	Provider incentives relating to:			Potential impacts on quality of care
	Cost per visit	Visits per time period	Length of episode	
Rate per visit	Reduce	Reduce	increase	<ul style="list-style-type: none"> • Reduce length of visitor quality of staff
Comprehensive monthly rate	Reduce	Reduce	increase	<ul style="list-style-type: none"> • Reduce length of visit or quality of staff • Provide service too infrequently
Comprehensive per-episode rate	Reduce	Reduce	Reduce	<ul style="list-style-type: none"> • Reduce length of visit or quality of staff • Provide too few home health services • Discharge prematurely
Bundling payment for hospital and posthospital services	Reduce	Reduce	Provide cost-efficient balance of hospital and posthospital services	<ul style="list-style-type: none"> • Reduce length of visit or quality of staff • Provide too few hospital/posthospital services • Discharge prematurely
Competitive bidding	Same as above units of payment for any given type of rate, but incentives maybe intensified if rates based on bidding are lower than rates based on historical costs. Also, possible reduction in access to services if winning bidders have insufficient capacity and/or losing bidders serve areas not reached by winning bidders.			

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstrations, *Demonstrations and Designs of Alternative Reimbursement Methods for Home Health Services*, HCFA Pub. No. 03290 (Baltimore, MD: HCFA, September 1989), table 3-2.

Quality Assurance

The quality and quantity of care provided to patients receiving home health services can be affected by the incentives inherent in the way Medicare pays providers. Incentives can take the form of higher payments for high quality care. Where quantity is one measure of quality (e.g., frequency of visits), then per-unit payment may provide good incentives. In other cases, workable measures of quality must be developed so that high quality can be rewarded (or low quality censured) by the payment system.

Competition can also be used to ensure quality. Even when Medicare payments are uniform across providers, providers in competitive markets may have to offer services of acceptable quality to attract Medicare patients and their physicians.

A 1989 study of alternative payment methods for home health services under Medicare examined these issues at the theoretical level (381).⁶ This study suggested that, while smaller units of payment (e.g., per visit) might result in increased utilization, larger units of payment (e.g., per episode) could result in reduced quality of services as providers attempted to cut costs of service (table 7-3) (381). Competitive bidding models, because they can have considerable

impact on the caseload, market share, and revenues of both losing and Winning bidders, also present serious quality and access concerns (381). These concerns might be exaggerated for a market as new and diffuse as HDIT. Nonetheless, these findings suggest that payment methods that create incentives for providers to cut costs (e.g., per episode, per diem, monthly rate, competitive bidding) should be balanced by more vigorous quality assurance and utilization review efforts (381).

When it is too difficult or costly to include appropriate incentives in the payment system, it may be necessary to develop a separate quality monitoring and assurance system. Payment can then be denied when quality measures fall below accepted standards. (Low quality of care can result from too much service as well as too little service. It is important to ensure that the system does not induce use of unnecessary care.)

HDIT services, because they can be more narrowly and specifically defined than home health services in general, may be more conducive to focused quality assurance measures. These might include Federal, State, and provider-level quality assurance initiatives and controls, implemented through survey and certification of providers, on an ongoing and systematic basis through providers'

⁶ Impact could not be examined directly because the intended projects to demonstrate them were never implemented.

internal quality assurance programs, and on an individual case basis (i.e., through preauthorization and retrospective review by an outside party).

Equity

Inequity among Medicare beneficiaries could arise if the payment system failed to ensure access to services in some geographic areas. It could also arise if patient cost sharing provisions fell disproportionately on one group or another, or if limits on coverage duration or scope served to deny benefits to certain groups of patients.

Inequity among providers may result from payment rates that do not account for differences in cost outside the provider's control, or from differences in the way services are reimbursed that may affect providers differently. For example, a single payment rate for all HDIT that was based on average costs over all types of therapy might disadvantage providers who specialize in a particular type of therapy that is more expensive than average.

Even if payment is equitable across all HDIT providers, equity across different settings of care may be difficult to achieve. There is little a priori reason to believe that home care is preferable to outpatient infusion for mobile patients with access to an outpatient provider, for instance. The method (and level) of payment chosen for HDIT, however, could easily cause an inequity between home and outpatient providers, resulting in possible unintended incentives to use one rather than the other.

Cost Control

Setting Payment Rates: Marginal Versus Average Costs

Cost control for the Medicare program, beneficiaries, and the health care system overall requires that payment is not excessive relative to production costs. Thus, regardless of the payment method chosen, the payment rate—i.e., the actual amount paid, regardless of the method in which it is calculated—is extremely important. From Medicare's perspective, the best payment rate is the lowest one that can be obtained without inducing undesirable changes in provider behavior (e.g., refusing to accept Medicare patients). For any individual provider, the response to a given payment

rate will depend heavily on whether that rate is above or below the provider's *marginal cost* (the provider's own production cost of serving one more patient) and the provider's *average cost* of serving all patients (i.e., total costs divided by total patients served).⁷

For the great majority of providers, setting rates below marginal costs would probably lead them to avoid serving Medicare patients (since they would take a financial loss on every patient). Exceptions might be publicly subsidized providers (e.g., public health departments) or providers that could treat the service as a "loss leader" to induce patients to also use other, more lucrative services. (Note that any given payment rate might be below the marginal cost for most providers but above marginal cost for others. The latter providers might still be willing to serve patients.)

If rates were set above marginal cost but below average cost, most providers would probably continue to serve Medicare beneficiaries. In this case, even though the rate fails to cover average cost, the payment received for each Medicare patient covers the extra cost that the patient generates and makes some contribution to the provider's fixed costs.

If payment just covers marginal costs, providers may be willing to serve Medicare patients if they are able to charge other payers more than average costs. Such cost shilling might raise concerns about the equitable distribution of cost among payers. A very simple model of home infusion provider behavior (app. D), however, suggests that rates between average and marginal cost would result in lower profits for providers rather than higher rates for other payers, so cost-shifting and *interpayer* equity is not a major issue.

Interprovider equity may be of somewhat more concern. In some cases, Medicare rates below average cost might endanger the financial viability of providers heavily dependent on Medicare patients. So, rates at this level could have an impact on access to services in some areas and for some types of providers.

Rates at or above average cost should be sufficient to induce providers to serve Medicare beneficiaries where such service can be efficiently

⁷Note that neither marginal nor average costs bear any necessary relation to charges. In fact, in order for a provider to make a profit in the long run, charges must be higher than average costs. Payments can be less than charges but still higher than average costs.

provided. They could also be viewed as covering Medicare's fair share of provider costs. Although rates above average costs (including a normal profit or return to invested capital) might be considered excessive in a world where all providers faced similar constraints and similar patients, there are some circumstances in which rates above measured average cost might be appropriate.

For example, it may be necessary to pay more than the average cost of an efficient-size operation to ensure that services are provided in areas that cannot support a provider of efficient size. Also, if the administrative costs of serving Medicare patients are significantly greater than such costs for other patients, then it may be desirable or necessary for Medicare to pay more than the average cost of serving all the provider's patients. Third, cost structures could differ from those postulated in appendix D. If marginal cost exceeds average cost (e.g., due to a limited supply of potential staff) and particularly if there are barriers to entry of new providers at an efficient size (e.g., startup costs), then it may be necessary to pay marginal costs (more than average cost) to induce supply beyond the minimum of the average cost curve.

Other Cost Containment Mechanisms

Because Medicare pays hospitals on a per-discharge basis, discharging a patient home early would result in temporary double-payment for that patient if the HDIT were covered. One private insurer with a payment method similar to Medicare's authorizes home infusion only for patients whose posthospital course of therapy is expected to be at least 7 days (243). This policy reduces the payer's short-term costs, but at the expense of also reducing hospital cost savings that might be reflected in future lower hospital payment rates.

Reducing hospital payments by some prescribed amount at the time an HDIT benefit is implemented would be another way to reduce the program costs of short-term double-payment. For example, patients discharged to HDIT could be treated in the same way as inter-hospital transfers, with the "transferring" hospital receiving a proportion of the full DRG rate, based on the number of days the patient was hospitalized. As yet, however, Medicare has little solid information on which to base such a policy. Unknown factors include the extent to which patients could be discharged sooner in the face of an

HDIT benefit; whether the ability to discharge varies among hospitals; and how hospitals would behave in the face of such a policy. The concept also violates one of the basic premises of Medicare's inpatient prospective payment system, which is intended to reward efficiency (and, where appropriate, short stays) and penalize inefficiency. A demonstration project could address the former issues, but the latter ones require a more fundamental policy change.

Administrative Feasibility

Cost and Complexity of Administration

It is not clear whether prospective payment or retrospective reimbursement methods are generally most easily administered. It is likely that the many HDIT providers who have not used Medicare cost reports (i.e., most providers that are not hospitals or HHAs) would find prospective rates easier to adopt than full cost reporting. On the other hand, administering the geographic and annual adjustments to prospective rates could be difficult and possibly costly for the Medicare program to do well.

Competitive processes may be the most administratively costly payment methods, because they require soliciting bids, making awards, and monitoring quality in every market area. Arizona's competitive-bidding-based Medicaid demonstration program, for example, has administrative costs equal to 12 percent of medical costs, compared with 4 to 7 percent for most other State Medicaid programs (212). Since the program showed a modest net savings overall, however, there may well be some substitution of administrative costs for medical costs in competitive bidding systems (212).

Government-set prospective rates may require the greatest difficulty obtaining accurate information to establish rates. In contrast to cost reimbursement methods (where the provider's actual cost is the rate paid) and competitive payment methods (where the competitive process effectively generates its own information through bidding or negotiation), government-set prospective rates require detailed information, of two types. First, the relevant costs used as the basis for the rates (e.g., average cost) must be measured or estimated reasonably accurately. Second, legitimate and acceptable variation in costs must be accounted for. Developing detailed information on variations and methods to account for differences, if found, could be complex.

Administrative burdens (e.g., learning Medicare cost reporting rules) can also affect provider participation. A generous payment rate may overcome resistance to paperwork burdens, but it may be preferable and less costly for the program to find ways to minimize the required provider documentation. Provider complaints about payment systems often mention payment delays, the need for multiple types of claims forms and procedures, unanticipated claim denials, and unreasonably low payment rates. To the extent that a payment system can limit these types of problems, provider participation is likely to be better.

One possible way to reduce administrative burdens for both Medicare and providers, whatever the payment method chosen, is to consolidate claims review and payment for HDIT within a few regional FIs. Precedents for such consolidation exist. TPN benefits are administered through only two national FIs. More recently, home health benefit administration has been consolidated among nine regional FIs. HCFA appears to be satisfied with the benefits of administrative consistency that have attended consolidation (399).

A final administrative consideration for Medicare is whether an HDIT benefit should be administered under Part A or Part B of Medicare. The question is not trivial, nor the answer obvious, because the components of HDIT as they are now covered under Medicare fall in both. DME and associated drug benefits are usually administered through Part B, and the Part B carriers currently have the greatest experience administering a home drug benefit as a consequence. On the other hand, home health services are usually administered through Part A intermediaries. Thus, if one objective is to ensure coordination of HDIT and other home health benefits, administration through Part A, or through FIs that administer both Parts A and B, may be indicated. Conversely, if HDIT patients were excluded from receiving concurrent home health benefits, it might make more sense to administer an HDIT benefit through Part B carriers.

Evaluating Payment Alternatives

The possible choices for HDIT payment are many and could include any of a number of variations on the payment models described above. This section assesses basic methods of payment according to the

tradeoffs they entail in the goals of a payment system.

Retrospective Charge- or Cost-Based Reimbursement

Cost- or charge-based reimbursement as a method of payment for HDIT (e.g., as in the existing Medicare home services model described above) offers the advantage of promoting provider participation and providing incentives for high quality care. This method would be easy to implement, since it fits with existing methods of payment for home equipment and services. Restricting payment to cost-based only would be slightly harder to implement, since many HDIT providers do not have experience with Medicare's cost reporting system.

The primary disadvantage of cost- and charge-based reimbursement is the lack of incentives for cost control. Both have inherently inflationary tendencies, because providers can recoup full costs (or, for charge-based reimbursement, greater than full costs) and thus have little reason to seek the best possible prices from their suppliers. Provider efforts to constrain their own costs are likely to occur only if they have a significant fraction of their business paid on some other basis. Since it appears that many (if not most) private insurers currently use some form of charge-based reimbursement for HDIT, this is not likely to be the case in the immediate future.

Despite its inflationary nature, cost-based reimbursement would not necessarily be more expensive to the Medicare program than prospective payment methods. If HDIT is provided with a common technology in accordance with well-established professional standards (for frequency of visits, necessary equipment, credentials of caregivers, criteria for termination of care, etc.) then there maybe little room for providers to inflate costs or provide extra services. If home care costs increased only slowly, and if prospective rates had to be set high (e.g., to ensure access in all areas, or because the ratesetting process was 'captured' by the industry), cost-based rates could be lower than prospectively set rates. Cost-based reimbursement would also have relatively low startup administrative costs compared with most other payment methods. Also, less quality assurance monitoring would be needed than with other payment methods.

Competitive Payment Methods

Competitive bidding approaches could be applied to HDIT. Services are fairly well defined and in many markets there are sufficient numbers of potential providers to allow for a truly competitive process. It would be possible to contract competitively for delivery of HDIT services to Medicare beneficiaries in individual markets across the country.

The principal advantage of competitive approaches are that market mechanisms are used to set rates. It would not be necessary to set rates uniformly high to ensure access in areas with high costs. Through competition, rates could be established well below average cost, probably close to marginal cost, without impairing the access of Medicare beneficiaries to service. Rates could be revised routinely to reflect changes in cost and technology.

The principal disadvantage of a competitive payment method is that the costs of administering such a system could exceed those for a prospective payment or cost reimbursement system. Although some competitive systems (e.g., Arizona's Medicaid program) have found that savings from low rates more than balanced the extra administrative costs in a comprehensive health care plan, Medicare might be hard-pressed to meet this standard due to the small market for HDIT. Competition would probably involve multiple bidding processes to cover the entire country. Also, as this method would give providers strong incentives to control costs, the same approaches to quality assurance would be required that are necessary with prospective government-set rates. Studies of existing competitive bidding programs have found that excluding quality as a criterion for award selection and inadequate monitoring of quality have been problems in some of these programs (380).

To be successful, this payment method requires that several providers be available in an area to compete. This may be a problem in sparsely populated areas with few providers. In addition, if the initial 'winners' in a bid gain sufficient market advantage, the long-term competitiveness of the market could be endangered. In particular, winner-take-all bidding may promote market concentration and

make future bidding harder to conduct (380). Long-term program costs could rise as a consequence.

Noncompetitive Prospectively Set Rates

Prospective rate setting offers greater direct government control over rates than is possible with cost reimbursement or competitive methods. This would promote efficient operations, but it might also lead to reduced quality of service (e.g., less reliability, less qualified staff, lower quality supplies, less internal quality assurance). The extent to which any cost saving would accrue to Medicare, rather than to provider profits, would depend on whether future rates were adjusted downward to reflect the savings. Inefficient providers and providers with high costs not fully adjusted for by a geographic wage index (e.g., those serving high-crime or low-volume areas) might find it difficult to continue serving Medicare patients.

As demonstrated by the proposed regulations pursuant to the MCCA, data limitations may restrict the exact form of prospective ratesetting that is immediately possible. In the proposed regulations, HCFA acknowledged some of the limitations of the data used to develop the rates and identified areas where better data may be needed. Data are most readily available on average costs (in HHAs) and charges. Little information is available on true marginal costs, or even average costs of freestanding HDIT specialty companies. However, estimates of average *variable* costs, which were the focus of the HCFA rates, may closely approximate marginal Costs.*

Updating Prospective Rates

Adjusting rates for changes over time may be even more difficult. Changes in the method of delivery in response to the new financial incentives or technology may make initial rates obsolete rather quickly. Much of the data used to establish rates comes from industry surveys. Once it is known that the surveys are used to set rates, providers may inflate the reported costs of providing services.

Under the MCCA, HCFA proposed to adjust rates among geographic areas using a wage index and to consider annual inflation adjustments. The adequacy of such a geographic adjustment depends on the extent to which the wage index reflects true cost

* Variable costs are those costs that change as output changes. (In the long run, most costs are variable, but in the short run variable costs are those such as supplies, transportation etc. that change as patient caseload increases or decreases.)

variations among HDIT. Cost of providing HDIT may vary with local costs of office space, transportation, and liability insurance as well as wages. There is no good information on the variation of such costs, so it is not clear whether the geographic wage adjustments would have been sufficient to ensure access of Medicare beneficiaries in all areas. If rates were based on average total costs, they would be at least as high as marginal cost even in the high-cost areas. In this case, the adequacy of an adjustment may be more of an issue of equity among providers than one of access.

Prospectively set rates are the basis for four very different models discussed earlier: the all-service per-month ESRD model, the per-diem MCCA and private sector models, the per-item private sector model, and the per-episode models that bundle home infusion with hospital or home health services. These models differ in two basic aspects: how they bundle services across time (e.g., per diem, per episode of care), and how extensively they bundle the various components of therapy (e.g., nursing and pharmacy services, equipment and supplies, drugs and ancillary services).

Bundling Across Components of Therapy

Bundling services together for payment, as HCFA proposed to do (under the MCCA) for HDIT nursing and pharmacy services, supplies, and equipment, reduces the incentive to provide extra services in the course of a visit. Bundling services, supplies, and equipment also encourages use of the most efficient combination of services. Its drawback is that it could also lead providers to skimp on provision of services if competitive forces or quality assurance procedures are not effective in ensuring provision of needed service components.

Bundling other components of therapy (e.g., drugs, routine laboratory services) into a single payment rate is also possible, although the Office of Technology Assessment (OTA) is not aware of any payers that currently do so for HDIT. The payment adjustments that might be necessary to accommodate different drug dosages and patient monitoring needs could be administratively taxing, at least until payers gain more experience with this therapy.

Alternatively, payments could be made separately for nursing care, supplies, equipment, pharmacy services, and all other components of care. As noted above, however, this is likely to lead providers to

supply as many such services as possible in order to maximize payments. Providers might also have an incentive to use expensive equipment, even if it was of little additional benefit to the patient. Monitoring the detailed itemization of supplies and equipment to preclude paying for unnecessary items could be administratively costly.

If unbundling was coupled with a diffusion of provider responsibility (from a single agency to multiple providers), then the quality of patient care could suffer from lack of coordination. In such circumstances it might be necessary to add (and pay for) a case management role to ensure coordination. An independent case manager could act to prevent use of unnecessary or unduly expensive services, but would probably be more costly than if the case management function was assumed by a provider.

Bundling Across Time

Any prospective payment method that bundles services across time creates incentives to cut costs and quality (e.g., by reducing the number of nursing visits) unless rates are high and there is strong competition to provide quality services to attract Medicare patient referrals. Per-diem rates may include a mild incentive to overuse services toward the end of therapy, if rates are higher than the daily costs of serving the patient, though such action would require the inattention of the patient's physician. Compared with per-episode rates, per-diem rates present less risk to the provider—persons with unusually long episodes of care will produce greater payments.

Bundling services across time for the purposes of payment may encounter information problems. In the hypothetical model described above, for example, in which HDIT would be “bundled” with hospital care, the lack of information regarding how to estimate per-DRG costs associated with HDIT might delay implementation of this method.

Other Issues

Paying for Drug Infusion Therapy in Skilled Nursing Facilities

For patients who require substantial professional nursing assistance and who cannot be treated as outpatients, treatment in SNFs is a potential alternative to hospital inpatient care. Medicare already covers drug infusion therapy in this setting. Despite

this apparent coverage, SNF-based infusion therapy may often be discouraged as unavailable, for four reasons.

First, most SNFs operate at close to capacity. In 1986, the average occupancy rate for SNFs in the United States was 92 percent (384). In 11 States, the average occupancy was over 95 percent (384). Consequently, admitting a patient to an SNF for extended drug infusion may often be much more difficult than prescribing home care for that patient.

Second, Medicare reimbursement for SNFs discourages the provision of most expensive therapies. Current reimbursement policy is to pay SNFs their costs, but these payment amounts are subject to a limit of 112 percent of the median costs for similar SNFs (74). Thus, any individual SNF is heavily discouraged from specializing in drug infusion therapy, which increases both supply and nursing costs.

Parenteral nutrition products provided to SNF patients are an exception to this reimbursement rule. When these products are provided by an outside supplier, who bills Medicare directly, their costs are not borne by the SNF. SNFs who likewise succeed in billing some drug infusion costs separately under Part B may be able to mitigate some of the disincentives for providing this therapy under Part A SNF payment.

Third, most SNFs do not have staff qualified to administer infusion therapy, and if most of a SNF's patients require less medically intensive care it has little incentive to recruit (and pay for) such personnel. Staffing issues may be a greater barrier than reimbursement to providing infusion therapy in many SNFs (133).

And fourth, Medicare coverage rules encourage SNF residents who develop a need for drug infusion to be rehospitalized for the therapy. By doing so, the beneficiary can often become re-eligible for Medicare's limited SNF benefits (133).

If Medicare covers HDIT, it may also wish to provide more balanced incentives to provide the therapy in SNFs for patients whose need levels make them expensive to Medicare to treat at home. Drug infusion therapy could, like parenteral nutrition, be recognized as a separate component and either billed directly by the provider or treated as a SNF "pass-through," not subject to the limits. Altern-

atively, SNFs could be reimbursed in a manner that was more directly related to the level of care provided. SNF reimbursement systems that link payment to patient resource needs are currently under development (300).

Higher extended-care payments for patients on drug infusion therapy would also benefit rural hospitals who must discharge such patients to swing beds for lack of other nonhospital providers (see ch. 6). Swing-bed care is reimbursed by Medicare at the average rate that Medicaid pays for SNF-level care in the different States (298). Swing-bed units might need higher payments to accommodate the higher service levels presumably needed to administer drug infusion therapy safely.

Physician Compensation and Ownership

HDIT requires substantial physician involvement. Physicians must assess the patient's medical condition, order the appropriate therapy, monitor the patient's ongoing health status at home, manage complications or changes in prescription needs, document all medical management, and respond to any emergencies. Furthermore, greater physician involvement and cooperation with other HDIT professionals probably leads to higher quality care (see ch. 5).

Except for reimbursement related to pre-discharge hospital visits and office visits during the course of therapy, however, physicians generally receive no compensation for performing these activities. The lack of direct payment for services that take place over the telephone or require substantial paperwork is a disincentive for some physicians to refer patients to home care generally (6,203). This may be one cause of the finding that, although the role of home health services has increased, physicians' involvement in home health care has decreased (12). The problem is exacerbated in the case of HDIT by the extensive and ongoing need for medical advice and decisionmaking during therapy.

At present, one way for physicians to receive greater financial rewards for the patients they refer to HDIT is by receiving some form of compensation from the home providers themselves. Compensation may take any of a number of forms. For example, according to some individuals interviewed by OTA staff, a physician may receive a "consulting fee" from the home provider, with the amount of the fee

linked to the number of patients referred by the physician.⁹ Alternatively, the physician may actually share ownership of the home provider itself, thus receiving a share of the profits of that provider, which result in part from the number of patients referred.

Physician ownership of health facilities is a common phenomenon. Over 8 percent of physicians who are members of the American Medical Association (AMA) report ownership interest in at least one health facility, and 6 percent refer patients to that facility (66). A study by the Office of Inspector General (OIG) found that 15 percent of physicians who bill Medicare have some kind of financial arrangement with a health care entity to which those physicians refer patients (383). Physician ownership is similarly common in the home infusion industry. For example, T², a home drug infusion company based in Georgia, is owned primarily by physicians who own stock in the company. As of 1990, the company owned 42 centers and managed another 51 centers (222). Furthermore, the independently owned centers managed by the company are themselves owned by physicians.

Financial inducements are not the only mechanisms by which providers may stimulate referrals. Hospitals, for instance, may offer physicians gratuities such as free office space in exchange for the relocation of the physician's practice to that hospital (383). The OIG study found that 8 percent of physicians billing Medicare receive nonfinancial compensation in exchange for patient referrals, such as office space rental agreements, employee arrangements, and management service contracts (383).

Inducements can be negative as well as positive. Hospitals that own HHAs, for example, may pressure physicians with hospital admitting privileges to refer their patients to the hospital's agency rather than to alternative sources of care.

Any business arrangement by which the physician receives financial compensation for the patients he or she refers to another provider raises both ethical and legal issues. Opponents to such arrangements have argued that they involve an inherent and unnecessary conflict between the physician's responsibility for the patient's well-being and his or her interest in financial reward (279,280). The

conflicts of interest may be especially strong if the physician's financial interest in the referral is not disclosed to the patient (279,280).

There is some evidence that physician ownership of health facilities is related to higher use of those facilities' services. Government studies of diagnostic imaging centers and clinical laboratories owned by referring physicians have reported that these facilities performed more tests, and the referring physicians ordered more tests, than comparable physicians and independently owned facilities (356, 383). A study of primary care physicians who owned their own radiology equipment likewise found that patients were at least four times as likely to have diagnostic imaging done if the patient's prescribing physician was self-referring, and charges for these procedures were often relatively high as well (157).

A recent study of physician-owned facilities in Florida found that results varied somewhat depending on the type of facility (321). This study found the most problems with clinical laboratories, diagnostic imaging centers, and physical therapy/rehabilitation centers. Physician-owned facilities in these categories had clearly increased costs, charges, and/or utilization, or were associated with greater access or quality problems, compared with comparable facilities. The report was not able to draw clear conclusions regarding problems with the other four types of facilities studied (ambulatory surgical centers, DME suppliers, HHAs, and radiation therapy centers). HDIT providers were not specifically examined in this study.

There is little consensus among physician associations regarding the acceptability of different ownership and other financial arrangements. The AMA, for example, holds that physician ownership of health facilities is both ethical and acceptable (13). The American College of Surgeons and the American College of Radiology takes the position that self-referrals are potentially unethical and generally not in the best interest of the patients (9). The strongest position on physician ownership has been taken by the Committee on Implications of For-Profit Enterprise in Health Care (drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine), which regarded it as unethical and

⁹ Such arrangements are not limited to home infusion therapy; for example, hospitals suffering great financial losses have offered physicians compensation disguised as "consulting fees" in order to recruit staff physicians (383).

unacceptable for physicians to have ownership interests in health care facilities to which they make referrals or to receive payments for making referrals (137). The committee recommended the use of physician compensation systems that break the link between the decisions physicians make in treating their patients and the rate of return they earn on investments in their medical practice.

In some circumstances, compensation for referrals is illegal. The Medicare and Medicaid Antikickback regulations prohibit offering, soliciting, paying, or receiving any remuneration, whether director indirect, for:

- referring an individual to a provider for the receipt of an item or service that is covered by Medicare or Medicaid; or
- purchasing, leasing, or ordering any item or service that is covered by Medicare or Medicaid.

Under the antikickback law, it is not only unethical but illegal for physicians to refer Medicare or Medicaid patients to a health care facility in exchange for remuneration. This provision has been upheld stringently by the courts. In a 1989 appeals court decision, the court found that the antikickback statute is violated unless payments are “wholly and not incidentally attributable to the delivery of goods and services.” (*U.S. v. Kats* [871 F.2d 105, 9th Cir. 1989]).

In contrast, it is not illegal under present statutes¹⁰ for physicians to invest in most kinds of health care

centers and refer their patients to those centers. Certain types of facilities have been singled out, however. The Omnibus Budget Reconciliation Act of 1989 (public Law 101-239) prohibits physicians who own or invest in clinical laboratories from referring Medicare patients to these facilities for laboratory testing.¹¹ The repealed MCCA would have prohibited payment for HDIT services provided by a company in which the physician ordering the services had a financial interest. (This prohibition was repealed along with the act.)

Despite its potential for abuse, physician ownership of health facilities may sometimes be not only acceptable but desirable. In some places, for example, a physician-owned health care unit may be the only such unit available; prohibiting payment for these services could be a barrier to basic access of health care.

Although ownership of HDIT providers was the focus of concern under the MCCA, drug infusion therapy services provided through a physician's own office may be at least as widespread a phenomenon. Banning this practice is tantamount to banning the dispensing of drugs in a physician's office and affects not only the physician's freedom to invest at will but his or her freedom to enter into certain kinds of personal practice. Ownership in both HDIT companies and office-based provision of HDIT raise similar concerns regarding referrals. Office-based infusion therapy raises a broad range of other issues as well, however, and policymakers may wish to distinguish between the two.

¹⁰ 42 U.S.C. 1395nn(b)

¹¹ This provision took effect on January 1, 1992.