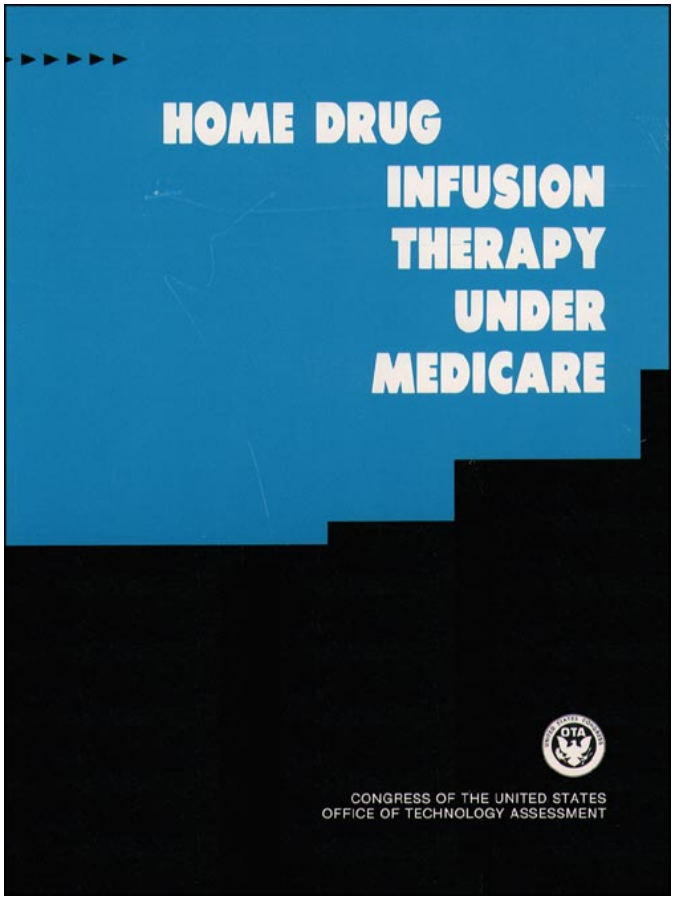
Home Drug Infusion Therapy Under Medicare

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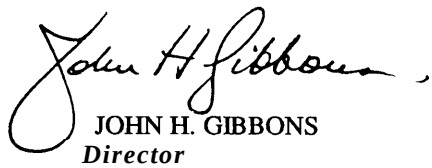
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Foreword

Home drug infusion therapy (HDIT) is an example of a mode of treatment that involves a multitude of new technologies: innovations in medical equipment and supplies, new drugs and drug protocols, and novel ways of organizing and delivering health care services. The rapid development and diffusion of HDIT is a product of our time; it has bloomed in an era in which the United States has searched with increasing intensity for ways to provide both better and cheaper health care to its citizens.

HDIT holds out the promise of making sophisticated, medically intensive drug therapies available to Medicare patients in their own homes, but the full consequences of a Medicare HDIT benefit are unclear. Because of interest in such a benefit and concern about its potential costs, the Senate Committee on Finance asked OTA to examine Medicare coverage and payment issues relating to this technology. This report was prepared in response to that request.

A related OTA report, *Outpatient Immunosuppressive Drugs Under Medicare, was* released in August 1991.



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List of Abbreviations

AHA —American Hospital Association
AIDS —acquired immunodeficiency syndrome
ALOS —average length of stay
AMA —American Medical Association
ASHP —American Society of Hospital Pharmacists
AWP —average wholesale price
BC/BS —Blue Cross and Blue Shield Association
BCBS/NCA-Blue Cross and Blue Shield of the National Capital Area
CFF -Cystic Fibrosis Foundation
CFR -Code of Federal Regulations
CHAMPUS -Civilian Health and Medical Program of the Uniformed Services
CHF -congestive heart failure
COP -conditions of participation
DHHS —U.S. Department of Health and Human Services
DME -durable medical equipment
DRG -diagnosis-related group
ESRD -end-stage renal disease
FDA —Food and Drug Administration (U.S. Public Health Service)
FI —fiscal intermediary
FR —Federal Register
FTE —full-time equivalent
GAO -General Accounting Office
G-CSF —granulocyte colony stimulating factor
GM-CSF —granulocyte microphage-colony stimulating factor
HCFA —Health Care Financing Administration (DHHS)
HDIT —home drug infusion therapy
HHA —home health agency
HMO —health maintenance organization
INS —Intravenous Nurses Society
Iv —intravenous
JCAHO —Joint Commission on the Accreditation of Healthcare Organizations
MCCA —Medicare Catastrophic Coverage Act
MCP —monthly cavitation payment
NABP —National Association of Boards of Pharmacy
NAHC —National Association for Home Care
NAIT —National Alliance for Infusion Therapy
NLN/CHAP-National League for Nursing's Community Health Accreditation Program
OBRA -Omnibus Budget Reconciliation Act
OIG -Office of Inspector General (DHHS)
OTA -Office of Technology Assessment (U.S. Congress)
PCA —patient-controlled analgesia
Pharm.D. -doctor of pharmacy
PICC —peripherally inserted central catheter
PPIC —Preferred Physician's Infusion Center, Inc.
PRO —peer review organizations
RN —registered nurse
R. Ph. —registered pharmacist
SNF —skilled nursing facility
SSA -Social Security Act
TPN —total parenteral nutrition
VNA —Visiting Nurses Association
VNA-LA —Visiting Nurses Association of Los Angeles

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Chapter 1

SUMMARY AND OPTIONS

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Chapter 1

SUMMARY AND OPTIONS

Introduction

Few changes in the organization and provision of health care in the United States have been as dramatic as the shift away from hospital inpatient care that occurred during the 1980s. The past decade witnessed tremendous growth in such diverse activities as the establishment of ambulatory surgery centers, physicians' office laboratory testing, and freestanding cancer and cardiac centers (272a). An especially striking change was the development and maturation of a system to provide intensive and highly sophisticated medical treatments to patients in their own homes. Home drug infusion is one such medical therapy.

Almost unknown before the late 1970s, home drug infusion therapy (HDIT) is now a major industry with net revenues in the billions of dollars (289,307). Its growth is no accident. Many health insurers view this technology as a potential cost-saver. Providers view it as a welcome way of enhancing revenues. Market analysts view it as an investment opportunity. And patients view HDIT as an opportunity to resume a reasonably normal life while continuing sophisticated medical treatment.

But the widespread enthusiasm for this novel mode of medical therapy has been tempered in some cases by uncertainty about its potential applications and possible hidden costs. Medicare, the Nation's single largest health care insurer, has no benefit that explicitly covers HDIT. The Medicare Catastrophic Coverage Act of 1988 (MCCA, Public Law 100-360), which would have extended coverage to this benefit, was repealed before it was ever implemented. In 1990, in the context of continued interest in such a benefit, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to revisit the implications of covering HDIT under Medicare and to analyze alternative ways of paying for this therapy. This report was prepared in response to that request.[1]

Although the literature on HDIT is considerable, most of it deals either with specific techniques and procedures or with the feasibility of providing this service. To gather information for this study, therefore, OTA relied not only on the published literature but also on site visits to HDIT providers, discussions with persons involved in HDIT, and data supplied by individual insurers and providers (see app. A). The remainder of this chapter presents a summary of OTA's findings and conclusions and contains options for congressional consideration.

Summary and Conclusions

What Is Home Drug Infusion Therapy?

OTA found that HDIT is a medical therapy that involves the prolonged (and usually repeated) injection of pharmaceutical products, most often delivered intravenously (into a vein) but also sometimes delivered via other routes (e.g., subcutaneously or epidurally).[2] Some drugs, such as antibiotics, maybe infused over relatively short periods (e.g., 30 minutes) a few times each day; others, such as analgesics to relieve extreme pain, maybe administered around the clock. All of these infusion therapies have in common the need for specialized equipment and supplies and skilled nursing care in order to be administered safely. At present, patients or their family caregivers[3] are usually, although not always, trained to perform some of these needed skilled services themselves.

Until the end of the 1970s, drug infusion therapy was almost always a hospital inpatient procedure. The components of care associated with this therapy (e.g., inserting the needle in the vein, regulating the infusion, monitoring the patient, and changing the dressing (bandage) around the needle's entry site) usually required the meticulous care of trained nurses to avoid life-threatening infections and allergic reactions. Indeed, these requirements still exist. During the late 1970s, however, a few hospitals and

[1] Another report prepared in response to the same general request, *Outpatient Immunosuppressive Drugs Under Medicare, was* released in September 1991.

[2] "Subcutaneously" refers to injections under the skin; "epidurally" refers to injections into the epidural space around the spinal cord.

[3] In this report, "family caregivers" refer to both immediate family members and other unpaid individurds (e.g., close fiends) who are trained to perform some of the nursing-related infusion services.

physicians began to train highly selected patients with prolonged infections (or their caregivers) to perform some of these procedures themselves at home (16,188,290,324). In the early 1980s, with the publication of successful results from some of these programs and the implementation of payer-induced constraints on hospital inpatient care, a new mode of therapy-and a new industry-was born.

This report deals with the drug and biological infusion treatments (including blood transfusions) being used in the home but not yet explicitly covered by Medicare in that setting. Medicare does cover total parenteral nutrition (TPN) in the home for individuals with long-term disabilities that prevent them from being able to digest food.[4] TPN has many similarities to the therapies discussed in detail in this report, and many providers of HDIT also provide TPN and other nutritional products and services. In fact, nutritional therapies still produce a substantial proportion of the revenues for the home infusion industry (34,307). However, because the purpose of this report is to examine other noncovered infusion therapies, TPN is discussed only as it is relevant to the issues surrounding HDIT.

Uses and Recipients of Therapy

The number of patients who currently receive drug infusion therapy at home is unknown but probably in the vicinity of a quarter of a million persons per year. A 1987 market analysis estimated that in the previous year, approximately 39,000 such patients received home treatment, and it predicted that over 225,000 would do so in 1990 (289). A more recent investment report estimated the 1990 market at roughly 200,000 patients (275). Given that the market has continued to grow, a 1991 estimate of between 200,000 and 250,000 persons in HDIT during the year seems reasonable.[5]

Most HDIT patients presently served are non-elderly adults. Two HDIT providers with data on patient age report that the great majority of their patients are between the ages of 18 and 65 (3,250). About 15 percent of each provider's patients are elderly (age 65 or over), a figure that includes some patients on nutritional and other infusion therapies as well as HDIT A survey of six national infusion specialty firms found that slightly less than 18 percent of patients are age 65 or over (256); again, this number included patients receiving TPN. Conversations with other providers suggest that many of them consider elderly patients on HDIT to be relatively rare. Thus, excluding patients on TPN, a "best guess" estimate is that about 10 to 15 percent of current HDIT patients are elderly. Based on these very rough assumptions, OTA estimates that between 20,000 and 35,000 elderly individuals received HDIT in 1991.

HDIT patients fall into a few major groups and many smaller ones. The first and largest group is composed of those patients who require intravenous (IV) drug therapy for infections (e.g., bone infections) that require prolonged treatment and are not usually susceptible to oral drugs. Persons with cancer make up another major group; these individuals may need not only antineoplastic drugs to combat the cancer but also antibiotics, analgesics, hydration, and other infusion therapies at times. A third category of HDIT recipients are those with AIDS. Like persons with cancer, those with AIDS may be treated with any of a number of therapies (e.g., antibiotics, antifungal medications, and blood transfusions) depending on their particular medical conditions.

Other categories of individuals whose conditions are sometimes treated with home infusion therapies include individuals with congestive heart failure, persons with certain immune disorders, pregnant women receiving infusions of drugs to prevent premature labor, and patients with severe anemia or other blood disorders who need blood transfusions. Some of these treatments are experimental or are not yet widely available in the home.

Components of Therapy

Drugs-At present, antibiotics and other anti-infectives are the most common drugs involved in home infusion therapy. Based on estimates by market analysts and other sources, it appears that about two-thirds of current drug orders for HDIT involve anti-infective drugs (34,193,193a).[6] Ap-

[4] "Parenteral" refers generally to methods of administration that bypass the digestive tract. TPN is nutrient solution that is administered intravenously.

[5] This number probably includes some individuals receiving outpatient clinic-based rather than home therapy, since the market analyses did not distinguish clearly between these two settings.

[6] Although antibiotics are responsible for about two-thirds of HDIT drug orders, only about half of HDIT patients receive antibiotics (193%256).

proximately another 15 percent of HDIT drugs are antineoplastics or pain medications. The diverse remaining group of drugs makes up somewhere between 10 and 20 percent of HDIT at present.

Equipment—Whatever the route of administration, HDIT requires two crucial pieces of equipment: the access device that is inserted into the body (e.g., an N catheter), and the Infusion device that controls the rate of drug flow. The choice of this equipment depends on the patient's condition, the length and type of drug therapy prescribed, and the preferences of the patient and provider. The methods of access and infusion control chosen, in turn, can affect the need for supplies and for nursing care and the overall cost of the therapy.

The continual emergence of new home infusion therapy technologies broadens the types of patients who can be treated at home and changes the parameters of service delivery. Some recently developed technologies have reduced the amount of skilled nursing intervention required for patients at home and made it easier for patients to self-administer complex drug regimens (see ch. 3). Nonetheless, despite the development of increasingly sophisticated infusion pumps over the past decade, less expensive gravity drip systems are still safe and appropriate for some patients receiving antibiotic and hydration therapies.

Services-HDIT involves a complex array of services that must be coordinated with each other. They also must be coordinated as a unit with any other home health care services and supplies the patient receives. Although the responsibilities and involvement of particular types of personnel vary greatly among HDIT providers, all HDIT requires that at least certain core services be provided in some way.

. *Pharmacy services* involve, at a minimum, compounding the drugs to be infused and being available to respond to emergencies and questions regarding the therapy.[7] Pharmacists' responsibilities often also extend to participating in patient education, **anticipating drug side** effects, dealing with nonemergency issues relating to the therapy, monitoring patients via conversations with nurses or patients themselves, monitoring laboratory results, and collaborating with physicians on prescription changes.



Photo credit: Ivion Corp.

New technologies such as this multiple-drug infusion pump allow patients to self-administer complex drug regimens at home.

- *Nursing services* include educating the patient and family caregiver regarding administration of the infusion and care of the infusion site,[8] dressing and infusion site changes, and in-home monitoring of the patient's health status. Nurses may perform a wide variety of other functions as well, ranging from overseeing the actual infusion to patient assessment and care coordination.
- *Physician services* provided by the patient's physician include ordering the home care, prescribing the therapy, overseeing the patient's progress through patient visits and monitoring laboratory and clinical reports, dealing with emergencies, and making changes in the therapy as needed. In practice, the extent of physician involvement in HDIT appears to be highly varied. Some physicians take a very active role—for example, seeing all patients in person at least twice a week and holding extensive telephone conversations with nurses and pharmacists involved in the therapy—

[7] **Larger infusion providers often employ pharmacy technicians to assist pharmacists in compounding drugs.**

[8] **Pharmacists, social workers, or other professionals may also be involved in aspects of patient assessment and education.**

while others have much less contact with the patient and professional caregivers during the course of the therapy.

- *Laboratory services are* necessary to monitor the patient's status and response to therapy as detected through blood samples and other tests. Most HDIT providers do not have in-house laboratories.

Based on numerous site visits and conversations with HDIT providers, patients, and others, it appears that most HDIT providers are skilled at coordinating the services specific to the home infusion therapy. For patients receiving other home care as well, however (e.g., basic home nursing, physical therapy, or respiratory therapy), the complex of HDIT-specific services must also be coordinated with these home health care services. Such coordination across different home care services may be particularly important for Medicare patients, but it is a service many HDIT providers are not currently well-equipped to offer.

Many of the tasks necessary for HDIT would be performed by a skilled nurse in a hospital setting. At home, however, these tasks can often be performed by the patient or a family caregiver who has been taught the proper techniques by a qualified health professional. Medicare beneficiaries are more likely than other patients to have disabilities that limit their ability to learn or perform infusion techniques and other most basic self-care tasks (e.g., dressing and bathing). Their spouses may also have functional limitations. Thus, OTA concludes, Medicare patients are more likely than other patients to require paid assistive services in order to receive medical care such as drug infusion therapy at home. If the frequency and intensity of professional services required by a home infusion patient are great (e.g., a functionally disabled patient on a 4-dose/day antibiotic regimen who has no family caregiver available), a skilled nursing facility (SNF) or other nonhospital institutional setting that offers 24-hour care might be a more reasonable alternative to hospitalization than traditional home care.

Current Medicare Coverage of HDIT

Medicare pays for "medically necessary" services and supplies associated with drug infusion when it takes place in hospitals, outpatient clinics, or physicians' offices. (Some of these settings (e.g., physicians' offices) may be subject to locally set limitations on infusion payments and coverage.)[9] Medicare does *not* have an HDIT benefit; the need for this therapy when provided at home does not qualify a beneficiary for Medicare coverage of any particular items. However, certain components of HDIT are sometimes covered by Medicare under existing benefits for beneficiaries in their own homes.

The core nursing services used in HDIT are sometimes covered by Medicare under the Part A home health benefit, while pharmacy services and supplies are sometimes covered under the Part B durable medical equipment (DME) benefit (table 1-1).[10] The home health benefit covers intermittent skilled nursing care, and home infusion therapy patients' need for such care would also qualify them for additional home health aide and therapy services. The Part B DME benefit covers reusable equipment such as infusion pumps and the supplies associated with such equipment. Some carriers also cover a wide variety of drugs when used in an infusion pump (365) (see ch. 6).

Current coverage of the core HDIT services has a number of problems. First, it is incomplete and fragmented; coverage is piecemeal, administratively split between Part A and Part B fiscal intermediaries (FIs-Medicare's administrative contractors), and highly variable. Some carriers, for example (the Part B FIs), interpret the DME benefit to include even coverage for antibiotics administered by gravity drip (365). Other carriers almost never pay for any drug through this benefit. Second, there are no guidelines for who can provide HDIT, and thus there are no minimum quality standards for such providers under Medicare.

A third problem with the existing benefit structure is that it tends to discourage the most independently functional patients from leaving the hospital. To be

9 Infusion is also sometimes provided in hospices and skilled nursing facilities (SNFs). Although Medicare "covers" the infusion in these instances, payment rates to hospices and SNFs are generally unaffected by whether the service is performed. These providers thus have a strong disincentive to offer infusion while a patient is served by the hospice or SNF.

10 Only the Part B DME benefit sometimes encompasses drugs. The Part A DME benefit that is subsumed under the home health care benefit specifically excludes drugs from coverage.

Table l-l—Existing Medicare Benefits Applicable to Home Drug Infusion Therapy

Benefit	Components of HDIT covered	Selected relevant limitations
Part A		
Home health services	Nursing, supplies,durable medical equipment (DME).	Patient must be homebound. Drugs *not* covered under home health DME benefit.
Hospice	Those components the hospice chooses to provide to its in-home patients.	Providing infusion does not affect hospice's flat-fee payment rate.
Part B		
Durable medical equipment	Pumps, other DME, supplies, selected drugs.	Drug coverage varies greatly by carrier. Disposable "pumps" not considered DME.
Laboratory services	Laboratory tests.	
Physician services	Physician visits, some office-based infusion therapy services provided to home patients.[a]	No payment for administrative responsibilities; may be local limits on office-based therapy.
Hospital outpatient services	On-site outpatient infusion therapy services provided to home patients.[a]	—

[a]Some patients, for example, may undertake their own daily routine infusion-related care but return to an outpatient clinic or office for more specialized services such as catheter site changes.

SOURCE: Office of Technology Assessment, 1992.

eligible for home health nursing benefits, for example, beneficiaries must be homebound-i.e., unable to leave their homes without some kind of assistance. And while nearly all carriers at least sometimes pay for infused cancer therapies (analgesics and antineoplastics) as part of the DME benefit, considerably fewer pay for antibiotics-and some of the latter pay only when a patient is so ill as to be already receiving other infusion therapies.

In addition to the core pharmacy and nursing components, Medicare routinely pays for the laboratory services associated with HDIT as part of the standard Part B laboratory benefit (table l-l). Medicare also routinely pays for physician services, including physician visits (home or office) to monitor the status of HDIT patients. However, the program does not pay for telephone or administrative time of physicians overseeing home care plans. Because of the level of medical monitoring needed for HDIT patients, the amount of time spent in these activities can be substantial. Consequently, the lack of payment for these services-and the relative generosity of payment for daily visits to hospitalized infusion patients—is a disincentive for physicians to discharge some patients to home care under the current system.

The Home Drug Infusion Industry

The development and shape of the HDIT industry has been influenced by two important factors. First, the development of the industry has followed past changes in Federal policies. Medicare coverage for home parenteral and enteral nutrition (begun in 1977) and the implementation of prospective payment for Medicare inpatient services (in 1983) both contributed to the explosion in the home infusion industry that occurred during the first half of the 1980s. If Medicare should choose to cover and pay for HDIT in the future, how it does so may have a similarly profound impact on the shape of the industry. Not only could the number of elderly patients being treated at home expand far beyond the estimated 20,000 to 35,000 now served, but Medicare's policies could serve as a model (or a caution) for other public and private insurance programs.

Second, the growth in the home infusion service industry-those organizations that provide the nursing and pharmacy services and products directly to patients—has been enabled by the technologies that have permitted drug infusion therapy to be self-administered in the home. Increasingly sophisticated infusion pumps, administration kits, therapy protocols, venous access devices, and drugs that need be



Photo credit: CADD-PCA@ Ambulatory Infusion Pump Model 5800, Pharmacia Deltec Inc., St. Paul, MN

Sophisticated infusion pumps have been developed for specific segments of the HDIT market. This pump delivers a constant dose of pain medication, with a special button that allows the patient to self-administer occasional larger doses as needed up to a preprogrammed maximum amount.

administered only once or twice a day have all contributed to the feasibility of home therapy for an ever-growing number of patients.

As manufacturers have developed new supplies and equipment, providers have become adept at incorporating them and marketing both products and services to patients, physicians, and payers. Provider success at encouraging HDIT, in turn, stimulates even greater effort in developing technologies for this market.

The present assortment of HDIT providers includes a few large (national or regional) infusion specialty providers that offer most of the basic services and products associated with drug infusion therapy, including pharmacy supplies and services, equipment and medical supplies, and specialty nursing. In addition, there are a multitude of smaller regional and local providers, for most of whom HDIT is a relatively small proportion of a larger business. These local providers include home health agencies (HHAs), community pharmacies, physicians, medical equipment suppliers, and hospitals.

In many cases, smaller providers may offer only one or two components of the therapy directly. A patient from a small town who is on HDIT, for example, might receive infusion-related nursing from the local HHA, pharmacy products and services from the local pharmacy, and an infusion pump from the local medical equipment dealer. In fact, it appears that many HDIT providers contract with at least one other type of provider to provide some components of the therapy. Where patients need routine as well as infusion specialty nursing, the routine nursing is ah-nest always performed by a separate agency (except where the HHA itself is also the primary home infusion provider) (see figure l-l).

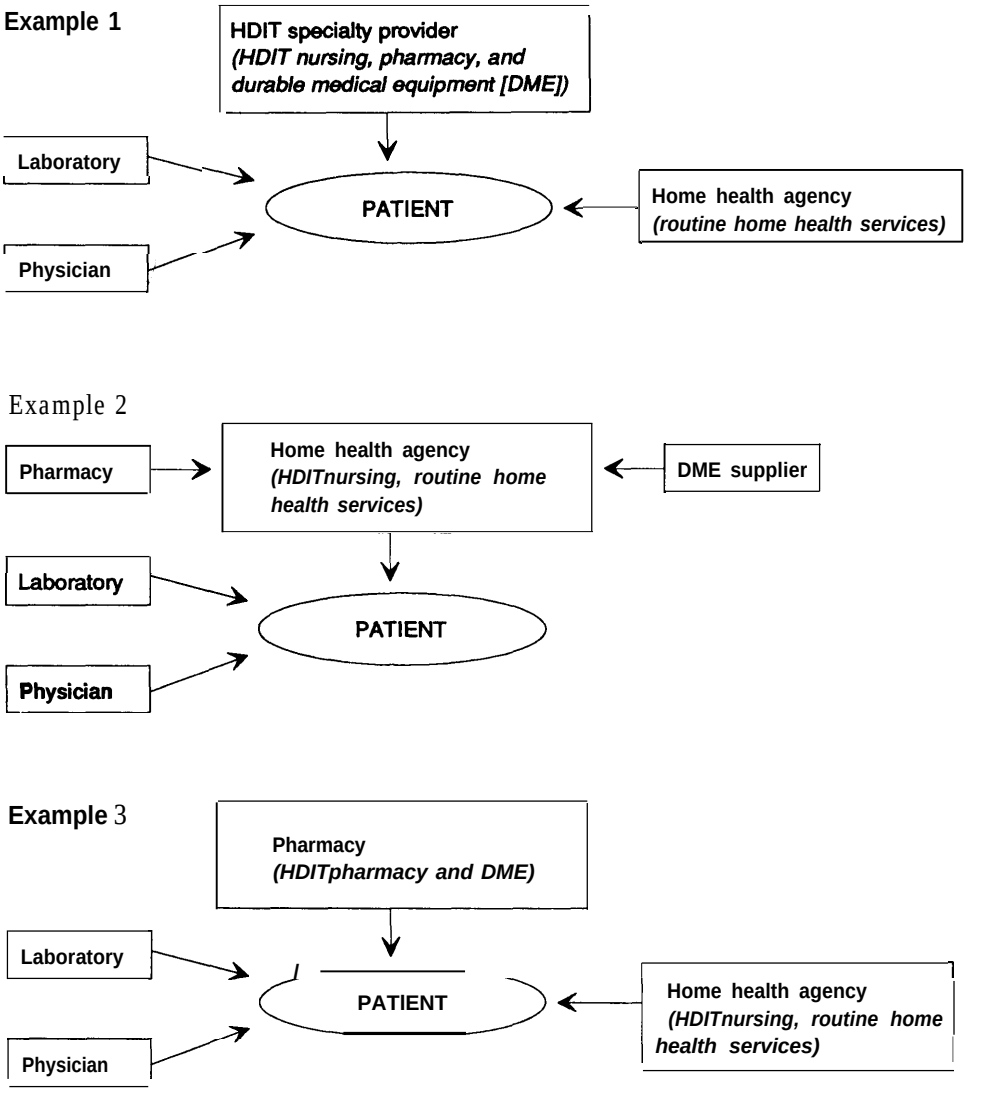
The continually expanding revenues and, apparently, relatively high profit margins that have been enjoyed by the HDIT industry thus far have facilitated and encouraged the entry of new providers into the marketplace, expanding access to HDIT services and stimulating the development of new products. The increasing revenues are in part due to the liberal reimbursement that these companies have often been able to garner. Future controls over what companies can charge Medicare patients for home infusion therapy might slow the growth of certain sectors of the marketplace.

Is HDIT Safe and Effective?

Home drug infusion technologies have become commonplace. Most are effective and can be performed safely in the home when patients are carefully selected and trained and home care providers have adequate procedures and qualified staff. However, HDIT is not without substantial risks. When those qualifications are not met, OTA believes that patients on home therapy can be at a high risk of adverse events, including severe infection, shock, and even death.

In a few cases, the effectiveness of the drug itself used in HDIT is open to question. For example, existing studies on long-term dobutamine, a drug sometimes used to treat severe congestive heart failure in the home, suggest that this use of the drug may actually be harmful for some patients (see ch. 2). Immune globulin is an example of a product that has some clearly indicated uses, but that is also finding use in a variety of conditions where its effectiveness is less well established (and its costs high).

Figure l-l—Three Examples of Potential Relationships Between Providers and Patients Receiving Both Home Drug Infusion Therapy (HDIT) and Routine Home Health Services



SOURCE: Office of Technology Assessment, 1992.

Infusion therapy carries some risks regardless of the setting in which it occurs. Although most complications (e.g., vein irritation at the catheter entry site) are minor if recognized and treated immediately, conditions such as sepsis (systemic infection) and shock (from drug allergic reactions) can be life-threatening. Mechanical complications of the infusion (e.g., air entering the vein) and equipment malfunctions can also cause serious medical problems.

Some risks (e.g., the risk of acquiring g serious secondary infections) are probably lower when patients are home than when they are in the hospital. On the other hand, in the hospital, constant nursing supervision and rapid access to sophisticated emergency care ameliorates many of the other risks of infusion therapy. In the home, there is rarely continuous professional monitoring, and emergency care is not available on site. Consequently, the most clearly appropriate drugs for the home are those in

which life-threatening side effects or complications are rare, and those in which most side effects are apparent when the first dose is given (which can be monitored in a hospital or physician's office). Many antibiotics fit this description. Although infused analgesics and antineoplastics require more care to be used safely at home, the need for these therapies lifelong by many patients may justify their use in this setting.

OTA found that, in addition to the choice of drug, patient selection and provider procedures are crucial to making the level of risk at home comparable to that in the hospital. Patients who are medically unstable (e.g., have a very high fever) are not appropriately discharged from the hospital. In addition, patients who have no supportive family caregivers, who are unable to understand and carry out infusion therapy procedures, or who are unwilling to continue therapy at home are at high risk of complications and are poor candidates for home care. Provider procedures, such as performing rigorous patient selection, requiring special pharmacist and nurse training, carrying anaphylaxis treatment kits, and requiring 24-hour on-call pharmacist and nurse availability, minimize risk. Physician involvement is also critical to the safe and effective delivery of HDIT services.

The relationship between patient suitability, provider procedures, and medical risk in HDIT warrants quality assurance efforts on the part of the Federal Government in the event of Medicare coverage. Quality assurance efforts should include some level of case review to monitor instances of possible poor-quality patient care. They should also include explicit and stringent conditions of participation that HDIT providers must meet to receive Medicare reimbursement. Such conditions can assure that although some direct patient care services may be performed under contract, certain functions (e.g., initial patient assessment, service coordination, periodic drug regimen review, clinical recordkeeping, and providing an ongoing and emergency point-of-contact for patient) remain the responsibility of the "primary" HDIT provider. This "primary" provider is the one that undertakes the responsibility for coordinating the HDIT and that subcontracts or arranges with others to provide those HDIT services it does not provide in-house.

Issues and Options for Medicare

Implications of Medicare Coverage

Substantial numbers of Medicare patients are currently receiving HDIT, although the exact number is unknown. As described above, OTA estimates that roughly 20,000 to 35,000 persons age 65 and over will receive this therapy in 1991, and of elderly persons the great majority is eligible for Medicare. In addition, some disabled Medicare beneficiaries probably receive HDIT

Many of the Medicare beneficiaries receiving HDIT at present have other insurance (e.g., private insurance or Medicaid) that presumably pays for the therapy. However, as described above, despite the lack of an explicit Medicare HDIT benefit, some beneficiaries do receive Medicare coverage for some of the components of HDIT some of the time. The frost decision regarding Medicare coverage of HDIT is whether to pass a comprehensive benefit.

Considerations regarding whether an HDIT benefit should be enacted are addressed in option below. Options 1 through 9 (summarized in table 1-2) then discuss some of the different forms such a benefit might take. Finally, options 10 through 19 present possible research and demonstration projects that might inform Federal policymakers regarding various aspects of HDIT These options, which could be implemented in either the presence or absence of a Medicare HDIT benefit, are summarized in table 1-3.

Option O: Enact a home drug infusion benefit under Medicare.

Many patients would prefer to receive drug infusion therapy at home rather than in the hospital, and when appropriate precautions are in place they receive good quality care. At present, however, existing "back door" mechanisms through which specific components of HDIT are currently covered result in fragmented and inconsistent coverage in which there are no qualifications required by Medicare for HDIT providers and no quality control of the overall set of services received by the patient. Thus, a Medicare HDIT benefit would offer enhanced patient benefits compared with the current policy.

The cost implications of extending Medicare coverage are less straightforward. In the short run, the addition of this benefit would almost certainly

Table l-2—issues and Options for Covering Home Drug Infusion Therapy (HDIT) Under Medicare

Basic Issue: Should Medicare cover HDIT?
Option O: Enact a home drug infusion benefit under Medicare.

(If so:)

issue 1: What routes of drug admlnlstratlon shouldbe covered?
Option 1A: Cover only intravenously administered drugs.

Option 1 B: Cover both intravenous and other routes of parenteral administration.

Issue 2: What drugs and conditions should be covered?
Option 2A: Cover drugs and conditions specified on a list devised by the Health Care Financing Administration (HCFA).

Option 2B: Permit fiscal intermediaries to determine specific covered drugs and conditions, based on general coverage categories and guidelines from HCFA.

Issue 3: Who should be eligible for the benefit?
Option 3A: Cover only patients who can self-administer their therapies (after initial instruction) or who have family caregivers to perform this service.

Option 3B: Extend coverage to all patients who can be safely treated at home, including patients who need assistance with their infusion-related or other home health care.

Option 3C: Extend coverage to patients who cannot self-administer, but limit the amount of assistive services such patients may receive.

Issue 4: Who should be able to provide and bill for HDIT?
Option 4A: For patients needing only HDIT, permit providers of different components of this therapy (e.g., pharmacy and nursing services) to bill separately for their respective components.

Option 4B: For patients needing only HDIT, require that a single certified home infusion therapy provider bill for all services received by that patient.

Option 4C: For patients needing both infusion and other home health services, permit a certified home infusion provider and the home health agency provider to bill separately for their respective services.

Option 4D: Require that the primary provider for patients needing both infusion therapy and other home services-i.e., the provider who coordinates services and submits a bill to Medicare-be a certified home health agency.

Issue 5: Where should a benefit be placed In Medicare's structure?
Option 5A: Make HDIT a Part A benefit.

Option 5B: Make HDIT a Part B benefit.

Option 5C: Make HDIT a benefit under both Parts A and B, depending on the patient's circumstance and concordant benefits.

Issue 6: Should benefit administration be consolidated?
Option 6: Require that the benefit be administered through a few regional fiscal intermediaries.

issue 7: What level of case review should be required, and by whom?
Option 7A: Do not require preauthorization for HDIT.

Option 7B: Require Peer Review Organizations (PROS) to preauthorize some or all HDIT patients.

Option 7C: Require fiscal intermediaries to preauthorize HDIT patients.

Option 7D: Require PROS to retrospectively review some home infusion patient claims.

issue 8: How should providers be paid for HDIT?
Option 8A: Pay for the various components of an HDIT benefit under existing payment mechanisms that apply to home health, durable medical equipment, and other benefits.

Option 8B: Pay for HDIT on the basis of actual costs, with a cap on the total costs allowed.

Option 8C: Pay a prospective per-diem rate for HDIT services.

issue 9: How should physicians be paid for HDIT-related services?
Option 9A. Pay physicians for their additional supervisory time in HDIT cases on the basis of existing fee-for-service methods.

Option 9B. Pay supervisory physicians a fixed rate (e.g., per patient or per day) for patients on HDIT.

Option 9C. Do not pay physicians for supervisory and advisory activities related to oversight of HDIT.

SOURCE: Office of Technology Assessment, 1992.

raise program costs, because Medicare cannot immediately recoup the financial benefits of shorter hospital stays. In the long run such a benefit could be cost-saving to the program, particularly if it were limited to independent patients who, when trained, needed little additional paid assistance. The benefit could be cost-raising in the long run, however, if Medicare were to pay for more costly home care in order to improve the quality of life during treatment for beneficiaries who need assistance to receive HDIT. The extent of long-run cost savings also depends on the ability of Medicare to bargain for low rates from providers, and its ability to identify patients who would be more costly at home and ensure that these patients are treated in alternative settings.

Covering HDIT would affect not only the Medicare program and HDIT providers and payers but also many facilities that are alternative sites of infusion therapy: skilled nursing facilities (SNFs), outpatient infusion providers, and hospitals. Outpatient clinics may be more appropriate settings than acute-care hospitals for some Medicare patients who need assistance with their infusion therapy, and SNFs may be more appropriate for many patients who need other assistive care as well. At present, however, SNFs have high occupancy rates and few empty beds, and most SNFs do not usually retain the

Table 1-3-Options for Conducting Research and Demonstrations Relating to Home Drug Infusion Therapy (HDIT)

Clinical studies
Option 11: Provide provisional or augmented coverage for drugs administered by HDIT providers participating in certain clinical studies.
Cost studies
Option 12. Examine the resource costs of providing HDIT and the economic characteristics of the HDIT industry.
Option 13. Examine the relative costs of providing drug infusion therapy in home and outpatient settings.
Option 14. Examine the use of basic home health services, and the need for infusion assistance, among elderly patients on HDIT
Payment studies
Option 15. Examine different potential methods of paying for HDIT.
Option 16. Examine the feasibility and effects of paying hospitals less than the full inpatient rate for patients subsequently discharged to HDIT.
Option 17. Examine alternative methods of paying for drug infusion therapy in skilled nursing facilities and hospital swing beds.
Option 18. Examine the effects of an HDIT benefit on rural and inner-city hospitals.
Quality studies
Option 19: Examine the outcomes of HDIT under various conditions (e.g., different types of patients and therapies) to determine which measures might be appropriately used as indicators of good- or poor-quality care.

SOURCE: Office of Technology Assessment, 1992.

in-house expertise to provide drug infusion therapy. They may be unwilling to accept drug infusion patients, or to treat existing patients in the nursing home, either due to lack of expertise or lack of reimbursement to cover the expense of intensive drug therapy.

For hospitals, covering HDIT would lead to lower payments in the future for some diagnosis-related groups (DRGs), to account for shorter average lengths of hospital stays and lower average costs in these DRGs. Hospitals unable to discharge patients home (e.g., due to the lack of a qualified home care provider in the area) would be disadvantaged despite their best efforts. This disadvantage will be minimized if these hospitals have "swing beds' '[11] to which they can discharge patients needing only drug infusion therapy and associated skilled nursing, and if they are adequately reimbursed for that care.

If current policies are unchanged, Medicare is likely to find itself paying for a substantial amount of HDIT in the future even in the absence of a defined benefit. Under current DME and home health rules, the actual coverage is increasing and will probably continue to do so, as Medicare's FIs use their discretion to cover drugs as well as the associated equipment, supplies, and nursing care. This coverage, however, will continue to be fragmented, uncoordinated, and inconsistent across areas. The absence of a coordinated benefit limits the ability of Medicare to assess, monitor, or influence the safety, quality, and effectiveness with which home infusion services are delivered.

Thus, OTA concludes that covering HDIT and placing defined requirements on providers and patients is likely to improve the quality of home care that Medicare patients receive. It may not save costs, however; to the contrary, it could easily increase Medicare spending. Program cost savings are probably more likely if the benefit places some restrictions on those who can use it.

Coverage Options

If Congress should decide to make HDIT a Medicare benefit, it must first decide what and who should be covered. Options 1 through 3 present possible alternative decisions regarding three coverage issues:

1. whether coverage should extend beyond IV administration to other forms of parenteral drug administration;
2. what drugs and medical conditions should be covered and how these coverage decisions should be made; and
3. whether patients who need assistance with their care (and have no family caregiver) should be eligible for the home infusion benefit.

Route of Administration

Option 1A: Cover only intravenously administered drugs.

Option IB: Cover both IV and other routes of parenteral administration.

[11] Swing beds are acute-care beds designated by a hospital to provide either acute or long-term care services. Medicine and Medicaid pay for care provided to swing-bed patients in qualifying rural hospitals.

Most drugs infused at home (e.g., most antibiotics) are administered intravenously. However, depending on the drug and the condition of the patient, drugs may also be infused into an artery (intraarterially), under the skin (subcutaneously), into the muscle (intramuscularly), into the abdomen (intraperitoneally), or into the areas around the spinal cord (epidurally or intrathecally).

In some cases, one of these latter modes of delivery is used because the drug itself is most effective, or causes the least complications, if administered in that manner. In a few cases, a drug may usually be most effective when administered intravenously, but a patient maybe unsuitable for IV therapy (e.g., because the veins are very fragile). Such a patient might instead get the drug by the next most favorable route (e.g., subcutaneously) .12

Choosing to cover drugs only if they are administered intravenously (as would have been the case under the MCCA) has the virtue of applying a rule that is unambiguous, simple to administer, and applicable to many of the drugs most amenable to home therapy (e.g., most antibiotics). Its drawback is that it will also exclude many drugs and patients that would otherwise be equally qualified for home therapy. It would also inhibit the use of drugs that might in the future be found equally effective and safer if given by some route other than IV.

In contrast, covering a broad general category of infused drugs in statute gives much greater latitude to the Health Care Financing Administration (HCFA) (or its FIs) to cover drugs delivered by means other than IV when such coverage is deemed appropriate at home. The great virtue of this option is its flexibility and adaptability to future changes in drug and device technology that make alternative delivery modes attractive. Its drawback is that it could be interpreted to include a wide variety of drugs and patients that were not intended to be included in a benefit. "Infusion," for example, might be applied to slowly administered liquid oral medications, or to drugs administered through a rapid injection as a one-time "shot. '

One strategy to address this drawback would be to define "infusion" carefully in statute, either by specifying excluded categories (e.g., fluids administered into the digestive tract) or included categories (e.g., intravenously and subcutaneously administered fluids injected over a period of at least 10 minutes). A second strategy would be to leave the definition of "infusion" and the delivery routes it encompasses up to HCFA.

Drugs and Conditions Covered

Option 2A: Cover drugs and conditions specified on a list devised by HCFA.

Option 2B: Permit fiscal intermediaries to determine specific covered drugs and conditions, based on general coverage categories and guidelines from HCFA.

Drug-level coverage decisions-whether to cover particular types of drugs for particular conditions or organisms-can theoretically be made at almost any level. The potential decisionmakers range from Congress, which could specify particular drugs in statute, to physicians, who could be permitted to prescribe (and receive payment for) any drug for any condition they deemed appropriate.

Greater levels of regulatory intervention in the decisionmaking process are associated with both greater checks on imprudent physician prescribing and less flexibility to accommodate new, effective drugs and treatment protocols. The choice of who should designate the drugs and conditions covered, therefore, becomes one whose point of compromise depends on the degree to which one values flexibility at the expense of oversight and consistency.

It is unlikely that Congress would choose to take upon itself the burden of identifying specific drugs and conditions to be reimbursed under Medicare. It is also unlikely that Congress would want Medicare to pay for all physician prescriptions. Option 2 thus outlines two intermediate alternatives. Option 2A exercises the greatest regulatory control, permitting coverage only for drugs determined by HCFA to be safe and effective in the home. In option 2B, the basic decision regarding what drugs are generally effective when delivered at home is left to the FIs-those contractors (usually private insurance companies) who would administer the benefit at the local or regional level on Medicare's behalf.

Federal-level decisionmaking would result in the greatest coverage consistency. HCFA has little experience in drug evaluation and is not currently involved in any drug approval process. If HCFA is

12 Alternatively, a patient with fragile veins might have a central catheter surgically implanted to avoid the need for repeated venous punctures.

required to approve drugs for home infusion use, either the agency must retain additional advisory personnel who have clinical experience, or another agency with such expertise (e.g., the Agency for Health Care Policy and Research, or the Food and Drug Administration) must be directed to assist HCFA in this task.

Local decisionmaking offers more adaptability but less consistency across locales (and, thus, presumably somewhat less equity across patients). Many FIs already have some familiarity with home infusion therapy in the context of either their Medicare or their private business, and they have medical advisory structures in place. If option 2B is chosen, administering an HDIT benefit through a few regionalized FIs might enhance coverage consistency (see option 6).

In addition to (or instead of) covering a basic defined set of drugs (whether set by HCFA or FIs), Congress could choose to provide provisional or augmented coverage for drugs that were part of specified demonstration projects. This possibility is discussed in option 11 below.

Patient Eligibility

Option 3A: Cover only patients who can self-administer their therapies (after initial instruction) or who have family caregivers trained to perform this service.

Option 3B: Extend coverage to all patients who can be safely treated at home, including patients who need assistance with their infusion-related or other home health care.

Option 3C: Extend coverage to patients who cannot self-administer, but limit the amount of assistive services such patients may receive.

Many beneficiaries who would prefer HDIT over hospital infusion might require assistance with their infusion or other health care needs in order to go home. However, providing assistive health services greatly increases the costs of care for a patient on HDIT, and the extent to which Medicare covers these services for HDIT beneficiaries would greatly affect Medicare expenditures.

Under option 3A, Medicare would cover HDIT only for patients who can demonstrate the capacity to administer the infusion without the assistance of a paid caregiver.[13] This alternative would restrict the benefit to a small number of patients and offers the surest opportunity to achieve program cost savings. However, it restricts the ability of disabled homebound patients, or those who (with assistance) might be able to avoid hospitalization altogether, to receive HDIT from a professional caregiver.

Under option 3B, any patient meeting basic medical appropriateness criteria could make use of the benefit. However, it would permit unlimited use of assistive home services, no matter how expensive, unless adjunct policies were also in place to limit these services.

Option 3C permits any patient to be eligible for HDIT but restricts the covered benefits that patient can receive. For example, the HDIT benefit might include coverage of daily nursing to accommodate patients with needs for occasional nurse-administered infusions (e.g., up to 10 visits or 20 hours of home skilled nursing per week). To avoid unwittingly paying for assistive services through the home health benefit in this example, HDIT patients could be disqualified from concurrent eligibility for that benefit. This alternative eliminates the possibility of paying for home care for patients who need very extensive services, but it could prevent some patients who currently qualify for home care services from receiving their infusion at home as well.

Alternatively, the HDIT benefit could be very limited in its coverage of assistive services but beneficiaries could be permitted (if they qualified) to retain home health benefit eligibility at the same time. Under this scenario, home health coverage for these dual-coverage patients could be limited to restrain utilization of assistive services. For example, HDIT patients who were homebound could be permitted concurrent coverage for home health services up to a stated maximum limit.[14] This alternative would allow for some assistance while providing an incentive for home providers to accept patients only if their anticipated assistive needs were few. However, it might also result in some underservice or rehospitalization of patients whose assis-

13 For example, a physician might be required to certify that the patient or family member could perform the infusion as a prerequisite for eligibility for the benefit.

14 For example, coverage for concurrent home health benefits could be limited to a dollar amount equal to some percentage of the *average* per-patient home health payment in that area.

tive needs were eventually greater than originally anticipated.

Option 3C might be somewhat complex to administer, since it presumes that the FIs involved can monitor HDIT and home health benefits simultaneously. Its implementation would be most straightforward if both benefits were administered by the same intermediary so that concurrent benefit eligibility could be detected easily (see option 5).

Administrative Options

The choice of how an HDIT benefit is to be administered can be made by Congress, or it can be left to HCFA to decide. Traditionally, the responsibility for administrative decisions has been primarily the purview of the executive branch of the government. Some administrative aspects of an HDIT benefit, however, have broad implications for the shape of the benefit itself. In these cases, Congress may want to provide HCFA with either statutory or nonbinding language to indicate how HCFA should address these issues.

Options 4 through 7 address some of the major decisions that must be made regarding administration of a home drug infusion benefit. These include:

1. how the primary provider responsible for the home benefit is specified;
2. whether an HDIT benefit should be placed administratively under part A or part B of the Medicare program;
3. whether the administration of the benefit should be consolidated under a few regional Medicare FIs; and
4. who should conduct appropriate case approval and review activities.

Provider Designation and Service Integration

Option 4A: For patients needing only HDIT, permit providers of different components of this therapy (e.g., pharmacy and nursing services) to bill separately for their respective components.

Option 4B: For patients needing only HDIT, require that a single certified home infusion therapy provider bill for all services received by that patient.

Option 4C: For patients needing both infusion and other home health services, permit a certified home infusion provider and the HHA provider to bill separately for their respective services.

Option 4D: Require that the primary provider for patients needing both infusion therapy and other home services-i.e., the provider who coordinates services and submits a bill to Medicare--be a certified HHA.

Some Medicare patients will need only HDIT and no additional assistive services in order to continue their medical treatment at home. (In fact, under option 3A above, only these patients would be eligible for the benefit.) For these patients, Congress could permit providers to bill Medicare as they sometimes do other payers, with one or many providers submitting bills according to the specific components of therapy they provide.

However, Congress may wish to ensure service integration and provider accountability by requiring that a single provider bill Medicare for all HDIT services provided to that patient. As was the case under the Medicare Catastrophic Coverage Act, the primary HDIT provider could be required to meet detailed criteria, as outlined in regulations, to be certified as a qualified HDIT provider.

Many Medicare patients medically stable enough to go home on HDIT, however, may need basic home health assistive services in order to function in this setting. Many (if not most) of the major HDIT providers are not Medicare-certified HHAs and do not provide basic home nursing, therapy, and home health aide services. For these patients, Medicare could permit separate billing by the respective HDIT and HHA providers (option 4C), with one or the other required to coordinate the two types of services; or, Medicare could require a certified HHA to bill for and coordinate all in-home health services provided to a given patient, including HDIT (which might be provided under contract to the HHA) (option 4D).

The coordination of infusion and other home health services is an important issue for beneficiaries, providers, and the Medicare program alike. For beneficiaries, dealing with two separate providers of home care services might mean duplications and gaps in services, with no single source of contact for coordinating or discussing the overall care with the patient. If a single HHA provider is responsible for both sets of services, coordination of these

services would be done by that HHA. If separate HDIT and HHA providers were recognized (as in option 4C), Medicare might want to require one of the providers (or an outside case manager) to undertake the coordination responsibilities.

For providers, permitting separate HDIT and HHA billing has the advantage of leaving the billing for a service to that provider with the most background in that service. There would be little need for HHAs to learn new HDIT-related billing and oversight responsibilities unless they undertook them voluntarily. Separate billing is preferred by many HDIT providers, because most are not currently certified by Medicare as HHAs (and some reportedly cannot do so because of certificate-of-need laws in their States that restrict new HHAs).

The Medicare program, on the other hand, might find single HHA-based billing simpler once HHAs learned the necessary procedures. Single billing would also reduce the difficulty of identifying and avoiding duplicate payment for HDIT and other home nursing services. Since home health is a Part A service unless the beneficiary has no Part A coverage, Medicare Part A intermediaries (rather than Part B carriers) would be the logical administrators to deal with claims if only HHA single-billing were permitted. However, this option might require considerable training of HHAs to familiarize them with HDIT and the necessary billing procedures.

Note that even if single HHA billing were required for patients receiving both HDIT and other home health services, Medicare could still permit HDIT-only providers to bill for infusion-only patients. In this case, claims might be handled by either Part A or Part B FIs, depending on the intent of Congress and the Medicare program (see option 5).

Administrative Placement

Option 5A: Make HDIT a Part A benefit.

Option 5B: Make HDIT a Part B benefit.

Option 5C: Make HDIT a benefit under both Parts A and B, depending on the patient's circumstance and concordant benefits.

The choice of administrative placement for an HDIT benefit affects who administers it and how easily it can be integrated with other Medicare benefits. Medicare Part A generally covers hospital, SNF?, home health, and hospice care and is administered through one set of FIs. Medicare Part B covers physician and laboratory services, hospital outpatient and ambulatory surgical services, and DME and is administered through a separate set of FIs. The Parts A and B FIs are private insurance companies, but only rarely does the same company fill both roles in its given locality.

At present, both Part A and Part B benefits overlap somewhat with a potential home drug infusion benefit. Existing home health benefits are usually under Part A and administered by 10 regional FIs, but home health services are also a Part B benefit for beneficiaries not eligible for Part A coverage. (In the latter case the benefit is still administered by the Part A FIs.) TPN, an existing infusion benefit, is a prosthetic device benefit under Part B and consolidated under two regional Part B FIs. DME benefits are usually administered through Part B FIs, but DME supplied by an HHA as part of the home health benefit is administered through the 10 Part A home health FIs. Hospice care, which sometimes includes home infusion therapy, is a Part A benefit; outpatient infusion and physician and laboratory services are Part B benefits.

Thus, the choice of where to place an HDIT benefit administratively depends in part on how it is to be integrated with existing benefits. If the benefit is to be linked with home health benefits, it would be administratively simplest to place it under Part A. If, however, it is to be entirely distinct from home health nursing, it would be simpler to place it under Part B, where some administrative experience with reimbursing for the component equipment and drugs is developing. Finally, it could be administered under Part A for some patients (e.g., those also qualifying for home health benefits) and under Part B for others (e.g., those needing no adjunct services) (see option 4).

The split of bills for patients receiving infusion services between Part A and Part B Fls could be problematic, since it would require all administrative contractors to gain some expertise in handling infusion claims and would increase variation in that handling. On the other hand, if home health and infusion providers were permitted to bill separately, Medicare might find it difficult to identify duplicate claims for home health nursing services.

One way to minimize claim-handling variation in the former case might be by consolidating FIs for the purposes of administrating this provision (option 6).

Fiscal Intermediary Consolidation

Option 6: Require that the benefit be administered through a few regional FIs.

Regardless of whether an HDIT benefit is placed under Part A, Part B, or both, Congress (or HCFA) may want to consider consolidating the administration of the benefit under a few regional Medicare administrative contractors. Such a consolidation has precedent both under Part A (for home health benefits) and under Part B (for TPN benefits).

The great advantage of consolidation is that the few administrative FIs can amass greater experience in administering the benefit, leading to more consistent coverage decisions, more rapid claims processing, and more information with which to update coverage decisions or payment amounts. In addition, the fewer number of administrative organizations means that the potential for widely varying and inconsistent coverage policies would be reduced. The advantage of greater claims experience might be especially important if the benefit were split between Part A and Part B, depending on the particular patient and circumstances (see option 5C).

The primary disadvantage of regional FIs is that the crossing of traditional contractor boundaries might pose difficulties for peer review organization (PRO) review, since PROS are located in each local contractor area. To overcome this disadvantage, the benefit might need to be overseen by a few regional PROS, corresponding to the regional intermediaries or carriers. To date, however, HCFA has relatively little experience in designating PROS with responsibilities across local contractor lines whose activities include prior authorizations.

Case Review

Option 7A: Do not require preauthorization for HDIT.

Option 7B: Require PROS to preauthorize some or all HDIT patients.

Option 7C: Require FIs to preauthorize HDIT patients.

Option 7D: Require PROS to retrospectively review some home infusion patient claims.

A critical element in the safe and effective delivery of HDIT is patient screening to ensure that hospital discharge (or, for nonhospitalized patients, drug therapy) is appropriate. Performing patient screening is one of the functions of HDIT providers. If they do it well, Medicare oversight—i.e., preauthorization-of HDIT patients at the onset of home therapy may not be necessary.

It may be difficult for Medicare to assure itself that HDIT patients are being appropriately screened, however, especially in the frost years when there is little experience with an HDIT benefit. In particular, Medicare may be justifiably concerned about premature hospital discharge. One detriment to a Medicare HDIT benefit is the strong financial incentive it could provide to both hospitals and home care providers to remove patients from the hospital, even when home care may be inappropriate or the patient is unwilling to be discharged. In the case of patients who are not hospitalized at the time HDIT is prescribed, Medicare may still wish to be assured that the patient can be safely treated at home. And in all cases, Medicare may wish to document who will be responsible for therapy and assure that the prescribed infusion therapy meets some basic criteria of medical necessity (e.g., oral drugs are not effective for the given condition).

There are two logical parties to perform HDIT preauthorization. First, the FIs who would later process the claim could conduct the review. Alternatively, PROS could give the preauthorization.

PROS are physician-run private organizations that contract with Medicare to review the appropriateness and necessity of medical interventions in a variety of settings, including hospitals. They are capable of detailed medical assessment and would probably be the most appropriate reviewers if the prior review were to involve an extensive discussion of the patient's therapy and condition. (The MCCA required PROS to conduct preauthorization review of all patients recommended for HDIT. In addition, HCFA's proposed regulations required PROS to approve prescription changes and other alterations made during the course of therapy, and to conduct retrospective review of a random sample of HDIT cases.) The disadvantage of this proposal is that PROS are poorly organized for quick response (as would be required where home discharge is imminent), and the extensive review that they are most qualified to provide is time-consuming, expensive, and would probably delay patient discharge somewhat.

FIs, in contrast, have traditionally had relatively less in-house medical expertise[15] but are more geared to day-to-day decisionmaking and detail. FIs thus might be more appropriate organizations to conduct preauthorization if the goal is a less comprehensive and less expensive check on basic appropriateness. For example, a FI-based prior approval mechanism might be simply to tentatively approve home therapy based on affirmative answers to a short list of screening questions, with final approval for payment made retrospectively by claims personnel on the basis of documentation in the record for these questions. Since brevity would be one of the goals of preauthorization in this case, quick turnaround (e.g., within 24 hours) could also be a requirement.

If FIs were judged to be the appropriate organizations to conduct prior review, it may still be desirable for PROS to participate in the development of the screening questions. Infusion professionals (e.g., infectious disease physicians, IV specialty nurses) could also be involved.

Prior authorization of all patients beginning HDIT may not be necessary, particularly in the long run if concerns about premature hospital discharge prove unwarranted. For drugs that are relatively safe (e.g., many antibiotics) and for which the indications are clear, issuing clear instructions to providers and conducting retrospective review may be sufficient.

Accordingly, in addition to requiring preauthorization of some home care cases, Congress or HCFA could require PROS to perform a detailed retrospective review of the appropriateness of care of a sample of claims to identify problems of care.[16] The review could be a simple random sample of cases (e.g., 10 percent of all claims). The review could be augmented by targeted review of all claims in certain categories indicative of possible problems (e.g., all claims associated with a beneficiary complaint; all claims in which the patient died or was rehospitalized within 30 days after home therapy; all claims for certain categories of drugs).

Payment Options

The way in which Medicare pays for HDIT would affect the shape of the industry, the willingness of providers to offer services to Medicare patients, the quality of the services provided, and the costs to Medicare. Options 8 and 9 deal with how Medicare might pay HDIT providers, whether providers will be required to accept Medicare assignment to serve Medicare patients, and the different ways Medicare might choose to compensate physicians for their services relating to a course of home infusion therapy.

Provider Payment Methods

Option 8A: Pay for the various components of an HDIT benefit under existing payment mechanisms that apply to home health, DME, and other benefits.

Option 8B: Pay for HDIT on the basis of actual costs, with a cap on the total costs allowed.

Option 8C: Pay a prospective per-diem rate for HDIT services.

The potential ways of paying for an HDIT benefit include both retrospective methods, in which the amount of payment is determined after the service is delivered; and prospective payment, in which the fee is determined before the service takes place. Retrospective methods include cost-based payment (the current method of paying for home health and hospital outpatient services) and charge-based payment (which historically has been the method of paying for DME and physicians' services). Prospective methods are varied and generally rely on some form of a fee schedule. Fees maybe established for each individual item or service, or these services may be "bundled' across time into, for example, a per-diem or per-discharge payment. Fees may either be set by the payer or be established on the basis of negotiation or provider competition.

Although any of these methods could theoretically be applied to HDIT, only three are sufficiently

15 Several carriers told OTA that their in-house medical expertise has increased over time and is now comparable to that in PROs. OTA has nOt independently evaluated this claim.

16 Under the MCCA, health maintenance organizations (HMOs) would have been excluded from PRO review for this service. However, HMOs that provide HDIT may face the same incentives as non-HMO hospitals to discharge patients to home care with inadequate support. Thus, PRO review of Medicare home infusion patients in HMOs and other capitated plans patients maybe justified.

well developed that they could, if desired, be implemented immediately. Of these, a method combining cost- and charge-based reimbursement would be the simplest to implement. In essence, this method would simply extend current rules (e.g., cost-based payment for home health services and charge-based payment for drugs, equipment, and supplies) where they applied and augment the existing system with refinements where necessary (e.g., better drug codes, allowances for pharmacy services). Non-HHA infusion providers might need to be permitted to bill for nursing (in a manner analogous to home health nursing visits) when the nursing visits were for infusion. This method is easily compatible with a policy that allows different providers to pay for different components of HDIT. It would probably have few negative consequences for quality or access to care, but it also offers the fewest possibilities for cost control.

All-cost-based reimbursement also offers incentives to provide high-quality, accessible care to Medicare beneficiaries, but it may be somewhat inflationary. Placing a capon allowable costs might reduce cost increases to some extent. All-cost-based reimbursement would be relatively easy to implement if HHAs were the primary providers, but HDIT-specialty providers have little experience with cost reporting. For these providers, this payment method would require some administrative effort. In any case, this payment method would probably require that a primary HDIT provider bill for all HDIT-related services in order for provider-specific Medicare costs to be assessed accurately.

Prospectively set rates (e.g., per-diem rates) for HDIT have been used successfully by private insurers, and more information is available to set rates now than at the time the MCCA was passed. This method offers the greatest possibility for cost control, but it could endanger patient access and quality of care if rates are low and quality of care cannot be monitored adequately.

If prospectively set rates are chosen as the method of payment for HDIT, bundling at least nursing services, supplies, and equipment into a single rate (or set of rates) may 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.

Competitively set prospective rates offer some advantages over HCFA-designated rates. Since rates are set according to the market based on provider bids, the data problems HCFA might otherwise encounter (e.g., setting rates too high or too low due to lack of information on provider costs) would be relatively less important. However, the need to compete and contract separately in each area of the country, and the need to monitor quality of care very closely, might make competitively set rates administratively very burdensome and costly. In addition, if contracts were awarded to only a few providers, the market advantage given to these providers might result in future market concentration. Thus, in later contracting rounds, there might be fewer providers bidding for contracts, and higher future payment rates.

Other payment methods-for example, bundling the payment for HDIT into the hospital's DRG payment—are also possible, but it would be difficult to implement these methods quickly. Some of these methods could be tested through demonstration projects if desired (see below).

Regardless of the payment method chosen, Medicare might want to take measures to limit beneficiary liability for charges greater than what Medicare pays. Private insurers have successfully implemented '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 could be one indicator that Medicare payment rates were set too low.

Physician Reimbursement

Option 9A: Pay physicians for their additional supervisory time in HDIT cases on the basis of existing fee-for-service methods.

Option 9B: Pay supervisory physicians a fixed rate (e.g., per patient or per day) for patients on HDIT.

Option 9C: Do not pay physicians for supervisory and advisory activities related to oversight of HDIT.

OTA found that active physician participation in a patient's home infusion care enhances the quality of that care and may help prevent potential untoward effects. In the hospital, physician involvement takes the form of frequent (usually daily) visits, each of which is often separately billable to Medicare. For patients in home care, however, physicians face substantially fewer opportunities to bill for services. Patients have fewer billable physician visits, while physicians spend time monitoring and adjusting therapy outside of visits and consulting with pharmacists, nurses, and patients over the telephone. None of these latter activities are currently reimbursable under Medicare.

Some physicians and home infusion providers have devised compensation mechanisms to counteract the financial disincentives related to payer policies. Some infusion providers, for example, reputedly pay physicians "consulting fees" in exchange for referrals. In other cases, physicians are co-owners of an infusion provider and thus share in profits that arise from referring patients to that provider. These arrangements may arise out of a legitimate desire to influence the quality of care provided and to receive some kind of reasonable compensation for the physician services associated with home care. Nonetheless, physicians have a virtual monopoly on referrals to HDIT providers. Physician compensation that is linked to the patient utilization of a particular provider introduces the possibility that physicians will refer patients to a higher-cost or lower-quality service in order for that physician to receive financial benefits. Even in a more benign form, physicians may be less active in seeking out the best provider for their patients when they share in the profits from a referral.

Medicare can, if it wishes, prohibit physicians who are co-owners of an HDIT provider from receiving payment, and existing Medicare anti-kickback provisions prohibit payment where physicians gain a fee for referral. If these forms of compensation are banned, however, many physicians will continue to be financially penalized for referring patients to home care. To avoid such a penalty, Medicare could pay physicians more comprehensively for the services they provide to HDIT patients.

Although there are many possible permutations on physician payment, one possibility is to permit physicians to bill for the time they spend in certain activities relating to overseeing the care of HDIT patients. Under this option, for example, physicians might be permitted to bill for the time spent in telephone consultation during a patient's course of home therapy. The advantage of this option is its simplicity and compatibility with current billing methods. Its primary disadvantage is its "blank check' characteristic; there are few ways to confirm that the time billed was actually spent on issues relating to a particular patient's HDIT. This option also sets a precedent for billing for telephone services and home care oversight generally, which could substantially increase Medicine costs.

A second option is to pay physicians a flat fee for the management of patients on HDIT. This fee could be a nominal one intended to cover only the average costs of oversight time exceeding what would be normally expected of a home care patient. Alternatively, the fee could be intended to cover all physician services relating to the infusion therapy during the course of therapy, including office and home visits. The amount could be set per day or per episode of therapy; it could vary depending on the type of therapy, the expected or actual duration of therapy, or other factors. There is a precedent for such a payment method; under the Medicare End-Stage Renal Disease program, physicians overseeing the dialysis treatment receive a flat monthly fee per patient. Additional billing is permitted for services performed for unrelated conditions (e.g., treating a broken arm).

A potential drawback of a flat comprehensive fee (rather than a daily fee) is the financial incentive to underprovide services. Under a comprehensive fee, fewer visits do not bring commensurately less revenue. Medicare could choose to assume that this problem would be minimal due to physicians' desires to provide good care to their patients, and their desire to avoid legal liability for poor care. Or, Medicare could set a mandatory minimum number of visits to ensure at least a basic level of service. Fees could vary depending on the type of therapy involved and whether the patient was on multiple therapies under the direction supervision of several physician specialists.

Research and Demonstration Options

A great many things that Medicare might want to know about HDIT are unknown or the subject of controversy. Areas of uncertainty range from clinical questions about the use of specific therapies in the home to questions about the needs of elderly HDIT patients and questions of costs and payment for HDIT. Many of these uncertainties could be addressed through specific research or demonstration projects aimed at investigating the particular issue.

Options 11 through 19 present examples of possible studies. Although this list is by no means exhaustive, it includes some of the major areas of controversy or uncertainty in which the findings could have a significant effect on the policies Medicare might choose to pursue. These projects could be undertaken to refine an existing basic HDIT benefit that had already been put in place. Alternatively, demonstration projects could predate a benefit, with the findings used to determine the shape of a later national HDIT Medicare policy.

Clinical Studies

Option 11: Provide provisional or augmented coverage for drugs administered by HDIT providers participating in certain clinical studies.

Medicare does not usually cover experimental drugs or procedures. Given the uncertainty about home use even for some drugs commonly used in hospitals, however, Medicare could choose to develop a framework to investigate drugs for their appropriateness in HDIT and their eligibility for Medicare coverage in that setting.

For example, Congress could authorize provisional coverage for drug infusion therapies for which insufficient evidence on home use in the Medicare population exists, but for which there are *a priori* reasons to think that the drug is likely to be effective in this setting and this population. Provisional coverage could be limited to drugs that had already received Food and Drug Administration (FDA) approval for use in the hospital, and participation in an organized research protocol (with enhanced data collection) that had been approved by HCFA could be required of providers for reimbursement during the provisional period. Such studies could gather economic as well as clinical information.

Congress could also choose to authorize provisional coverage for some projects involving drugs with greater clinical uncertainties. Such projects might be used to address the relative effectiveness of an approved drug for a new use that was likely to be long-term and applicable to the home setting. For example, a project might provisionally cover dobutamine while collecting and examining the evidence that this drug actually does improve health when used as an intermittent long-term therapy. This type of project involves greater potential for provisionally funding drugs that will eventually be proven ineffective, however. Congress might wish to distinguish between studies of drugs that have previously been proven effective for a particular use in the hospital, and those for which effectiveness for the use itself is still in doubt.

Cost Studies

Option 12: Examine the resource costs of providing HDIT and the economic characteristics of the HDIT industry.

An important problem in determining an appropriate method and level of Medicare payment for HDIT is that the true costs of providing HDIT are unknown. Existing studies of the "costs" of HDIT often rely on provider charges to estimate costs. However, charges (i.e., provider-assigned prices) and costs (the true resource costs faced by the provider) are by no means the same and may vary across therapies, patients, and providers. Differences in provider-specific costs would be especially useful for Medicare to understand, so that payment rates can accommodate those differences where desired without unnecessarily increasing Medicare expenditures.

Option 13: Examine the relative costs of providing drug infusion therapy in home and outpatient settings.

Although the focus of this report is home therapy, drug infusion therapy is also sometimes provided in outpatient clinics. Proponents of outpatient therapy argue that it enables better quality control, greater physician involvement, and greater economic efficiencies because there is no need to send a nurse to every patient's home. If these arguments are valid for at least some patients and providers, Medicare may want to be especially careful not to put in place an HDIT benefit that would unintentionally discourage patients from outpatient infusion therapy where

it is available. Understanding the relative costs and uses of outpatient and home therapy would help inform such a policy.

Option 14: Examine the use of basic home health services, and the need for infusion assistance, among elderly patients on HDIT.

As mentioned above, an HDIT benefit could be limited to patients who (with family caregiver assistance) were capable of self-care. Many other beneficiaries, however, might also prefer HDIT to institutional treatment. A major question for Medicare is the extent of this potential demand, the characteristics of the patients who would use adjunct services, and the costs of the home health services involved.

A demonstration project could examine this question either generally or for one or more groups of beneficiaries of particular interest to Medicare. Groups of potential interest, for example, might be homebound beneficiaries currently receiving home health services who develop a need for infusion therapy; patients needing help with the actual infusion but no other home health assistance; and patients for whom it is anticipated that inpatient hospitalization for drug therapy could be avoided if HDIT and other home health services were available.

Payment Studies

Option 15: Examine different potential methods of paying for HDIT.

Although cost- and charge-based payment methods could be applied to HDIT with relatively modest administrative effort, other methods are more difficult or rely on less certain information. Per-diem methods, for example, are feasible at present, but the information on which appropriate rates could be based is scanty. A demonstration project testing a preliminary rate for its effects on provider participation and quality of care would add greatly to that information base. Other payment methods that could be tested include:

- competitive bidding methods;
- per-diem methods in which components were "bundled' in various ways (e.g., the per-diem rate might include or exclude such items as DME, nursing services, pharmacy services, and laboratory services);
- per-patient prospective payment methods based on episodes of care; and
- hospital-based payment, in which the hospital might receive the HDIT payment as a DRG add-on and be responsible for providing or arranging for all care, whether inpatient or outpatient.

Option 16: Examine the feasibility and effects of paying hospitals less than the full inpatient rate for patients subsequently discharged to HDIT.

A major barrier to Medicare program savings in the first years of an HDIT benefit is the fact that hospitals are entitled to receive the full DRG-based payment for all patients in that DRG, even if a patient is discharged to HDIT after a few days. One possible solution to reduce expenditures would be to pay hospitals less than the full DRG amount for patients discharged to HDIT. For example, if the discharge destination on a patient's hospital bill is recorded as HDIT, the inpatient stay might be treated as a transfer, with the "transferring" hospital receiving a prorated amount depending on the actual inpatient length of stay.

A philosophically troublesome aspect of such a "transfer" policy is that it contradicts the basic theoretical structure of Medicare's hospital payment system, which is intended to reward hospitals that behave efficiently (e.g., by discharging patients quickly). In addition, the actual effects of such a policy on hospital discharge behavior and Medicare expenditures are unclear. For example, hospitals might simply encourage physicians to discharge such patients only at the point where the hospital had recouped the full DRG payment. On the other hand, such a policy might have some effect on expenditure reduction even in the event of such hospital behavior.

Option 17: Examine alternative methods of paying for drug infusion therapy in SNFs and hospital swing beds.

Where patients are medically stable but need continual supervision or substantial assistive care in addition to their drug infusion therapy, institutional care that is less intensive than hospital inpatient care may be the most appropriate and least expensive. At present, however, there appear to be considerable staffing-related problems and some financial disincentives to providing drug infusion therapy in SNF

and swing-bed settings. Other methods of paying for such therapy in these settings warrant investigation.

Option 18: Examine the effects of an HDIT benefit on rural and inner-city hospitals.

If an HDIT benefit is put in place, most hospitals will be able to discharge relevant patients to a home care provider in their area. These hospitals will benefit financially by doing so, because they receive the full DRG payment for each patient regardless of the actual length of the inpatient stay.

Some hospitals, however, may not be able to discharge patients easily. Some rural hospitals, for example, may be located in areas with no qualified HDIT provider. Inner-city hospitals may serve patients who live in high-crime areas that local providers may be unwilling to serve. Thus, it is possible that hospitals in these categories may be financially disadvantaged, through no fault of their own, by their inability to discharge patients to HDIT and lower their costs. A study of hospitals that are potentially at risk of being disadvantaged could determine whether Medicare policies needed to accommodate this factor.

Quality Studies

Option 19: Examine the outcomes of HDIT under various conditions (e.g., different types of patients and therapies) to determine which measures might be appropriately used as indicators of good- or poor-quality care.

Medicare's ability to monitor the quality of care provided under an HDIT benefit is crucial. Participating providers, for example, might be required to show that their record on care quality was acceptable before being able to renew their Medicare certification. Indicators of poor quality could be used to screen cases for more in-depth retrospective review. And certain payment systems, particularly prospective payment systems with fixed rates, include incentives to underprovide care, making Medicare's ability to detect and censure poor-quality care even more critical.

Despite their importance, measures of the quality of HDIT are not well-studied and reported in the literature. Examples of measures that deserve study include:

- average complication rates (e.g., the rate of catheter-related infection) among different types of patients and therapies;
- differences in complication rates, rehospitalization rates, and other factors that are related to different drug delivery systems (e.g., whether patients on simple gravity drips experience more complications of therapy than patients using more sophisticated infusion devices);
- the different factors that affect patient satisfaction with therapy; and
- whether provider-specific factors (e.g., contracting v. providing in-house services) are consistently related to other possible quality measures.

Because HDIT technologies have been changing so rapidly, even professional associations that establish care standards (e.g., the frequency with which catheters should be changed to avoid infection) are hard-pressed to keep their recommendations in pace with technological change.

The Federal Government could fund studies to examine various outcome measures to determine which measures can most appropriately be used to monitor the quality of HDIT care provided to Medicare beneficiaries. Such studies could be done in conjunction with a new HDIT benefit or as part of a larger demonstration study of HDIT.

Chapter 2

THE SAFETY AND EFFECTIVENESS OF HOME DRUG INFUSION THERAPY

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Chapter 2

THE SAFETY AND EFFECTIVENESS OF HOME DRUG INFUSION THERAPY

Overview

Introduction

There is no well-established or formal definition of home drug infusion therapy (HDIT). In this report, HDIT describes treatment that consists of prolonged (or continuous) injections of drugs that are administered in the home, usually repeatedly.

Spurred by public- and private-sector policies that have encouraged alternatives to hospital inpatient care, HDIT has become a widespread mode of therapy affecting hundreds of thousands of people. Market analysts have estimated that between 1986 and 1990 alone, the number of patients treated outside the hospital with drug infusion therapy grew from approximately 39,000 to between 200,000 and 225,000 (275,289). These numbers may overestimate the number of patients actually treated at home, since they probably include some patients treated in outpatient clinics.

HDIT encompasses an increasingly wide variety of specific drugs and therapies, each with its own characteristics and considerations. Accordingly, this chapter describes how the drugs used in HDIT are delivered, the patients who use this therapy, the drugs they use, and the safety and effectiveness of those drugs when infused in the home.

Properly speaking, HDIT should include only drug therapy. In this report, however, it is often also used for the sake of simplicity to include some therapies other than drugs (e.g., hydration and blood transfusions) that are not usually covered by Medicare when administered in the home. Another related therapy, total parenteral nutrition (TPN), is currently covered; it is discussed in this report only as a separate form of infusion therapy and is not considered part of HDIT.

Summary of Conclusions

- Most prescriptions for HDIT are for anti-infective drugs. However, the **number and variety** of drugs that are being infused in the home are large and increasing.
- In general, HDIT can be provided safely and effectively if adequate precautions are taken against side effects of the therapy and potential adverse drug reactions. The safety and effectiveness in any given situation, however, depends critically on the particular drug and the condition of the patient receiving it. The safety and effectiveness of anti-infective drugs in individuals who are healthy in all respects except the infection being treated are well-established. Therapies used in patients with cancer and acquired immunodeficiency syndrome (AIDS) are also well-established, but their use in the home requires special caution because of the disabilities of the patients treated, the multitude of therapies these patients may require, and the potential toxicity of many of the drugs they receive.
- The ability to deliver infused drugs safely in the home HDIT has enabled the use of therapies in ways that might rarely have been tried if, instead, the patient had to be continually hospitalized. HDIT thus can sometimes make new, more powerfully effective drug protocols more attractive to try. However, it also may encourage the rapid transfer of new drugs and new protocols into the relatively unmonitored home setting without a thorough testing of their effectiveness in this setting or an appreciation of their costs. Dobutamine, for example, is being infused at home despite evidence suggesting that long-term therapy increases mortality rates in some patient groups. Immune globulin infusion is likewise a small but growing home technology whose effectiveness has been documented in a few cases but whose actual uses are expanding extremely rapidly and whose costs may be extremely high.
- Even among well-established home infusion therapies, questions exist that can probably only be answered by research and experience that involve home patients. For example, despite the fact that most HDIT in the United States involves drugs administered intravenously, recent studies from Europe and Britain

suggest that some therapies (e.g., pain management, heparin, immune globulin) may be administered more simply, safely, and effectively subcutaneously.

Drug Administration

Considerations in Oral v. Parenteral Administration

From both the patient's and the physician's perspective, the most desirable route of administration is the one that is easiest, most effective, and poses the lowest risk of side effects and potential complications. Oral administration often fullfills these criteria and is the route of choice for most drugs. Sometimes, however, oral administration is inadequate or inappropriate, necessitating *parenteral drugs* (i.e., drugs not administered into the digestive tract). Factors that can lead to a preference for parenteral over oral administration include the drugs's absorption and metabolic characteristics, its side effects, its predictability, and the condition of the patient.

Drug Absorption

To perform their intended functions, drugs must be delivered to the relevant tissues of the body. Orally administered drugs are first absorbed from the digestive tract and then carried in the blood to the tissues. The absorption of drugs from the digestive tract is highly variable. Some drugs (e.g., aspirin) are almost completely absorbed into the blood. Others, such as the aminoglycosides (a class of antibiotic), pass through the entire digestive system with less than 1 percent absorption (129).

Drugs that are not adequately absorbed cannot attain blood levels sufficient to treat the particular condition and must, therefore, be administered parenterally. The factors that determine the absorption of a particular drug include its physical and chemical properties (e.g., its volubility), the presence of other substances in the digestive tract, the relative acidity of the digestive tract, and the time it takes the stomach to empty (11).

Even if a particular drug is eventually completely absorbed, the rate of absorption may be too slow to produce a therapeutic concentration in the blood (i.e., the concentration that is necessary to treat that condition). Or, the absorption rate may be so rapid that high concentrations of the drug cause adverse reactions (11).

Drug Metabolism

The degree of metabolism that a drug undergoes—i.e., its biological decomposition-also influences the route of administration. While many drugs can be given orally with little loss of biologic activity, others are metabolized by digestive enzymes and their potency either reduced greatly or lost entirely.

Human immune globulin, for example, is a naturally occurring substance composed of antibodies produced by a particular kind of white blood cell. Immune globulin has been used to supplement the deficiency of normal antibodies in certain individuals with rare diseases (e.g., severe combined immunodeficiency syndrome) whose bodies are unable to manufacture their own (54). If given orally, immune globulin would be digested and biologically destroyed. Consequently, it must be administered parenterally in order to retain its function.

Side Effects

Many drugs can be administered effectively either orally or parenterally, but the side effects they produce may vary depending on the route of administration. Orally administered drugs often can cause nausea and vomiting, which limit the amount of that drug that can be given by mouth.

Methotrexate, for example, can be given either orally or intravenously-i. e., directly into a vein. When used in small doses to treat diseases such as psoriasis and rheumatoid arthritis, oral methotrexate is usually well-tolerated and has minimal side effects (216). When used as an antineoplastic agent to treat certain cancers, however, the dose of the drug that is required to be effective would produce severe digestive upset if administered orally. Thus, for this use it is usually administered intravenously.

Predictability of Parenteral Administration

Parenterally administered drugs are subject to far less variability of absorption than oral drugs, and the amount of delivered drug that reaches therapeutic concentration is far more predictable. Consequently, drugs that have a narrow 'therapeutic window,' the range in which a drug is effective but does not produce toxic effects, are often administered parenterally so that the amount absorbed can be better controlled. In addition, intravenously administered medication is essentially completely absorbed, be-

cause it goes directly into the blood. This characteristic usually leads not only to more predictable but to higher drug levels than those produced by any other route.

Erythromycin, for example, is a common antibiotic used to treat a variety of infections. After a single oral dose of 500 mg, peak concentration of active drug in the bloodstream ranges from 0.3 to 1.9 ug/ml, depending on the particular preparation used. The same 500-mg dose administered intravenously, however, results in a peak blood level of approximately 10 ug/ml, a level 5 to 30 times greater than that obtained by oral administration (129).

Patient Condition

The choice of oral v. parenteral administration depends not only on the characteristics of the drug but also on the condition for which it is being used. Urinary tract infections, for example, are usually susceptible to oral antibiotics, while bone infections are not. In the past, parenteral administration has been the only feasible way of administering sufficient antibiotic to achieve adequate concentrations of the drug in the bone. A recently developed class of antibiotic, however, the fluoroquinolones, can now be used orally to treat some bone infections (125).

A patient's physical condition can also affect the route of drug administration. A patient with oral cancer, for example, may be unable to swallow oral analgesics and may require parenteral narcotics even for mild to moderate pain (37).

Routes of Parenteral Drug Administration

Most commonly, drugs that cannot be administered orally and must be infused over a period of time are administered intravenously. For certain drugs, however, or for patients in whom access to the vein is for some reason compromised, drugs may be infused into the body through other routes. Some antineoplastic[1] drugs, for example, may be infused into an artery *(intraarterially)*, which carries the drug directly to the site of the tumor. *Intraperitoneal drugs*, administered into the peritoneal (abdominal) cavity, are also occasionally used for certain cancers. Drugs used to manage pain in terminal cancer may be infused in the *epidural* or *intrathecal* spaces surrounding the spinal cord, where they are absorbed directly into the central nervous system. Some drugs may be infused under the skin *(subcutaneously)* rather than by other routes, either because the drug is best absorbed that way, because of a reduced risk of serious infection, or because the patient's veins are not adequate to sustain venous infusion.

As with the choice of oral v. parenteral drugs, the choice of which parenteral route of drug administration to use depends heavily on the characteristics of the drugs and its limitations (table 2-l). For example, some drugs (e.g., many antibiotics) are effective when given either intravenously or *intramuscularly* (injected into the muscle). Intramuscular injection, however, can cause severe pain and discomfort if the drug must be administered gradually, frequently, or in large doses. In such cases, intravenous (IV) administration is usually preferred.

The preferred route of parenteral administration can change over time with new evidence. Two recent reports, for example, suggest that heparin-usually administered intravenously when used as extended therapy for deep-vein thrombosis[2]-can be safely and effectively administered subcutaneously as well (165,271). Furthermore, one of these reports suggests that subcutaneous administration reduces the need for continual laboratory monitoring and dose adjustment, enhancing the drug's attractiveness for home use (271).

Conditions Treated With HDIT

Individuals on HDIT may be treated for any of a wide variety of diverse medical conditions, ranging from high-risk pregnancy to congestive heart failure. The most common conditions treated with HDIT, however, fall into three general categories: infections, cancer, and AIDS. Each of these conditions and the home infusion therapies that may be used to treat it are described below.

Infections

The classic candidate for HDIT is the patient who has an infection requiring a long course of IV antibiotics, but who has no other complicating conditions. These patients are likely to have two of the characteristics that allow for home IV administration and make this form of drug delivery an

[1] Antineoplastic drugs act against cancerous tumors.

[2] Deep-vein thrombosis is the formation of a clot in a main vein of the trunk or extremities, inhibiting blood flow.

Table 2-l-Some Characteristics of Common Routes of Drug Administration'

Route	Absorption pattern	Special utility	Limitations and precautions
Oral ingestion	• Variable, depends on many factors	• Most convenient and economical • Usually safer than other methods	• Requires patient cooperation • Availability potentially erratic and incomplete for drugs that are poorly soluble, slowly absorbed, unstable, or extensively metabolized by the liver
Intravenous	• Absorption circumvented • Potentially immediate effects	• Valuable for emergency use • Permits titration of dosage • Suitable for large volumes and for irritating substances, when diluted	• Increased risk of adverse effects • Must inject solutions slowly, as a rule • Not suitable for oily solutions or insoluble substances
Subcutaneous	• Prompt (from aqueous solution) • Slow and sustained (from repository preparations)	• Suitable for some insoluble suspensions and for implantation of solid pellets	• Not suitable for large volumes • Possible pain or necrosis from irritating substances
Intramuscular	• Prompt (from aqueous solution) • Slow and sustained (from repository preparations)	• Suitable for moderate volumes, oily vehicles, and some irritating substances	• Precluded during anticoagulant medication • May interfere with interpretation of certain diagnostic tests (e.g., creatnine phosphokinase).

[a]Other routes include topical, transdermal, otic, sublingual, buccal, intranasal, rectal, ocular, intraarterial, epidural, and intrathecal.

SOURCE: Adapted from A.G. Gilman, L.S. Goodman, R.W. Rail, et al., *Goodman and Gilman's The Pharmacological Basis of Therapeutics* (New York, NY: McMillan Publishing Co., 1985).

attractive alternative. First, many of these patients have stable medical conditions and require little additional medical attention besides their course of antibiotics. Second, as discussed later in this chapter, most IV antibiotics are relatively free from serious side effects and adverse reactions, making them less dangerous than other IV therapies. Consequently, antibiotics and other anti-infectives make up about two-thirds of the HDIT market (34).

Osteomyelitis (infection of the bone) was one of the earliest conditions to be treated at home with IV antibiotics (see, e.g., 16). This condition occurs when bacteria invade the bone, such as after a compound fracture that opens the broken bone to the outside environment. Long courses of therapy with high concentrations of antibiotics are often required to treat this condition; treatment of 4 or more weeks duration is common (106,148,325). In published studies of home and outpatient IV antibiotic use, high proportions of the patients studied-over half in some reports-had osteomyelitis (16,136,148,267). The condition remains a popular one for treating with outpatient or home antibiotics. A recent report of drug infusion therapy in one large outpatient practice found that 32 percent of the patients treated had osteomyelitis (340).

Cellulitis (infection of the skin and surrounding tissue) is another condition frequently treated with home IV antibiotics. This condition, often found in persons with impaired immune systems, can result when bacteria enters a break in the skin and the body's immune system is unable to fend off the invading organisms. Persons with diabetes, for example, often have poorly functioning immune systems, and even a minor local infection can develop into a life-threatening problem. Other infections sometimes treated with home IV antibiotic therapy when oral drugs are insufficient include respiratory infections (e.g., pneumonia and bronchitis), urinary tract infections, pelvic inflammatory disease, and endocarditis (infection of the heart valves). Examples of the relative prevalence of these conditions in programs that treat patients with home or outpatient IV antibiotics are presented in table 2-2.

The relative prevalence of conditions treated varies considerably among providers. For example, in contrast to the two programs represented in the table 2-2, the National Alliance for Infusion Therapy reports that in a sample of its members, Lyme disease (which was not even separately listed in the reports of the programs represented in table 2-2) accounted for 13 percent of patients treated with antibiotics (256).

Sometimes, IV antibiotics are used to combat repeated infections in persons with underlying disorders that predispose them to these diseases. Persons with cystic fibrosis, for example, are espe-

Table 2-2—Relative Prevalence of Conditions Treated With Home or Outpatient Intravenous Antibiotic Therapy in Two Programs

	Percent of patients with condition	
Type of infection	Poretz, 1989	Tice, 1991
Bone and joint	38	41
Skin/skin structure	22	18
Respiratory	13	2
Urinary tract	8	1
Endocarditis	2	3
Gynecologic	3	19
Other	12	16
Total	100[a]	100

[a]Total may not add to exactly 100 due to rounding.

SOURCES: D.M. Poretz, "Home Management of Antibiotic Therapy," *Current Clinical Topics in infectious Diseases* 10:27-42, 1989; A. D. Tice, "An Office Model of Outpatient Parenteral Antibiotic Therapy," Reviews *of Infectious* Diseases 13(Suppl2):S184-8, 1991.

cially susceptible to certain respiratory infections (64). Traditionally, these individuals required frequent hospitalizations to treat the infections. A number of studies published since the mid-1970s, however, have documented safe and effective home treatment of cystic fibrosis patients with IV antibiotics (128,290,328,400).

More recently, investigators have begun testing prophylactic (i.e., preventive) IV antibiotic regimens for persons with cystic fibrosis (88,102). The long-term effectiveness of these regimens in preventing infections, however, is still uncertain.

Cancer

Individuals with cancer make up another large group of patients utilizing HDIT. Many cancer treatment protocols require frequent administration of antineoplastics, toxic antitumor drugs that must be delivered directly into the bloodstream due to their inherently caustic properties. One of the therapeutic regimens for metastatic[3] breast cancer, for example, involves the continuous infusion of vinblastine, an antineoplastic drug, every 3 weeks for a 5-day period (1 16). Rather than returning to the hospital for each successive round of treatment, some patients on this (and other) protocols are receiving their treatment in the home. The particular antineoplastic that is used, more than the type of cancer being treated, determines the appropriateness of home IV use (35).

Unlike patients with simple infections, cancer patients may receive a number of different infusion therapies simultaneously. In addition to antineoplastics, persons with cancer may at sometime during the course of their disease receive:

- parenterally administered narcotic analgesics to relieve severe pain;
- TPN or hydration[4] to help to minimize the anorexia and physical deterioration caused by the disease and by the drugs used to treat it;
- blood transfusions necessitated by the anemia that results from both the therapy and the underlying disease;[5] and
- IV antibiotics to combat infection. (The suppression of bone marrow that results in anemia also makes cancer patients susceptible to infection).

All of these therapies are sometimes administered at home. In addition, the patient may receive other drugs, such as antinausea drugs, that are administered as periodic rapid injections (rather than as slow infusions).

AIDS

Like persons with cancer, those with AIDS often require a multitude of parenteral therapies to combat the disease and the secondary effects of some of the medications used to treat it. Characteristic infusion therapies that might be administered in the home include:

- Anti-infective drugs such as gancyclovir (an antiviral agent) and amphotericin (an antifumgal drug) to treat opportunistic infections;
- TPN to maintain in adequate weight and nutrition; and
- Blood transfusions to treat the anemia that results from both the underlying disease and the

[3]Metastatic disease is the spread of a malignant cancer to distant parts of the body.

[4]TPN (total parenteral nutrition) is the administration of nutrients directly into the bloodstream. Hydration is the administration of simple fluids (e.g., dextrose solutions).

[5]Antineoplastic drugs act by inhibiting the growth of rapidly dividing cells, such as those in the tumor. However, they also inhibit the division of normal cells that divide rapidly, such as the blood precursor cells in bone marrow, causing anemia (a lack of red blood cells). The cancer itself can also enter the bone marrow and inhibit normal growth in these cells.

drugs used to treat it.[6] Azidothymidine, for example, was until very recently the only drug approved by the Food and Drug Administration (FDA) to treat the infection that causes AIDS. A major side effect of this drug, as with antineoplastic drugs, is its toxic effect on the blood precursor cells in bone marrow. Gancyclovir and amphotericin also produce anemia.

Pain medication and adjunct injectibles, such as antinausea drugs, are also sometimes used by individuals with AIDS. (Aerosolized pentamidine, an inhaled drug sometimes prescribed for pneumonia in AIDS patients, is widely used in this population and is often also supplied by HDIT providers.)

The Safety of HDIT

Considerations and Risks Infusion Therapy

All medical therapies carry some degree of risk. Although drug infusion therapy has been a routine inpatient procedure for many years and is generally safe, adverse outcomes do occur, even in closely monitored hospital settings. Each year almost 1.5 million patients of the 17 to 24 million that receive IV therapy (mostly as inpatients) experience some form of complication (345). Of these, about 3,000 die from complications of IV therapy (93).

Complications of infusion therapy fall into two general categories: local and systemic (i.e., not confined to a specific area of the body). Table 2-3 summarizes some of these potential complications, the more common of which are described briefly below. Although the complications described are applicable to most types of infusion therapy, IV therapy is the most common, and complications are described in this context.

Local Complications

Phlebitis--Perhaps the most frequently encountered complication of any infusion therapy is phlebitis-inflammation at the site of the catheter insertion. (If there is also a blood clot at the IV site, the condition is termed thrombophlebitis.) Depending on the situation, this complication has been estimated to occur in 3.5 to 70 percent of *all* patients receiving IV medication (61). Phlebitis can result from chemical (e.g., a highly irritating drug), mechanical (e.g., catheter-caused irritation), and biologic causes (e.g., contamination of the drug container). Careful attention to proper procedure can reduce the rate of infection (see ch. 3). If left untreated, infectious thrombophlebitis has the potential to cause more severe complications, including septicemia and death (see below).

Infiltration-Venous catheters that are improperly placed or have dislodged from the vein deliver the infused solution into the tissue around the vein rather than into the vein itself. This complication can be extremely painfull, especially if the infusate (the infused solution) consists of some kind of irritant. In the case of ant.ineoplastic therapy for cancer patients, an IV infusion that has infiltrated can be particularly devastating. Antineoplastic drugs are, by nature, very caustic, and infiltration of these agents into soft tissue can cause widespread tissue destruction, necessitating tissue debridement, skin grafting, and other surgical procedures (398).

Table 2-3-Potential Complications of Intravenous Therapy

Local complications
Phlebitis, thrombosis, thrombophlebitis *(inflammation and/or blood clot of a vessel)*
Suppurative thrombophlebitis *(infected blood clot in a blood vessel)*
Infiltration and extravasation (seepage *of infusate into surrounding tissue)*
Cellulitis *(infection of the soft tissue)*
Nerve, tendon, or ligament damage
Hematoma *(accumulation of blood within tissues)*
Collapsed blood vessel
Venous spasm
Pain
Systemic complications
Septicemia, bacteremia, pyrogenic reation (diffuse, blood-bome infection)
Embolism *(obstructlon of a Hood vessel)*
Pneumothorax, hemothorax, hydrothorax *(air, blood, or fluid in the chest cavity)*
Hypersensitivity/allergic reaction

SOURCE: Adapted from C.W. Delaney and M.L. Lauer, *Intravenous Therapy: A Guide to Quality Care* (Philadelphia, PA: J.B. Lippincott Co., 1988).

[6] The need for blood transfusions maybe reduced somewhat with the introduction on the market of the drug erythropoeitin, recently approved by the FDA to treat anemia in AIDS patients.

[7] Septicemia is the presence of disease-causing bacteria in the bloodstream.

Systemic Complications

Sepsis--One of the causes of phlebitis is infection at the site of IV catheter insertion. Untreated infectious thrombophlebitis can lead to severe consequences. If the patient's immune system is unable to destroy the invading organism, it can continue to multiply and infect virtually all recesses of the body. This condition, known as sepsis, can be fatal; each year 20,000 to 30,000 patients die from catheter-related sepsis (79). Careful attention to early signs of catheter infection or even early sepsis can mitigate the impact of this devastating condition.

Embolism—Particulate matter that is introduced into the venous system by an IV catheter (the embolus) becomes lodged in small vessels and stops circulation (embolism). If the tissue supplied by that blood vessel does not have adequate collateral circulation, it dies. The consequence of this complication depends on where the embolus lodges. Because of the dynamics of circulation, an embolus from a venous catheter usually ends up in the lung, causing a variable amount of destruction-and even death-depending on the size of the embolus.

Embolic material maybe of several sources. The most frequent form of catheter-associated embolism is a blood clot that has formed at the site of thrombophlebitis, then broken loose and lodged elsewhere in the bloodstream (93). Improperly inserted catheters can also break off or dislodge and form a source of embolic material. Air, if mistakenly introduced into the catheter, can also serve as an embolic source (93).

Allergic Reaction—Almost all IV drugs have the capacity to produce an allergic reaction. The manifestation of that reaction, however, can range from a mild skin eruption to circulatory shock and death. Unless there is a prior history of drug allergy in the particular patient, allergic reactions are not predictable. Safe administration of parenteral drugs thus requires prompt identification and early treatment of reactions.

Drug allergies are relatively common. For example, about 2 percent of the population is allergic to penicillin (387), and an estimated 400 to 800 deaths in this country are attributable to this cause (320). Elderly patients (who may have more exposure to a drug and, therefore, more chance to develop an allergy to it), patients with a history of other allergies, patients with a history of a prior drug reaction, and patients with certain underlying conditions all represent groups at risk for drug allergy. Certain biological and chemical characteristics of the drug also affect the frequency with which it causes allergic reactions in those exposed to it.

Other Drug Reactions-Besides allergic reactions, drugs can cause a variety of other problems. Some of these are predictable occurrences and are frequent, recognized side effects of the drugs that are used. Other complications are less predictable and are termed *idiosyncratic*. For example, patients treated with the antibiotic chloramphenicol have a small but distinct chance of developing complete destruction of their bone marrow. Only about 1 out of 30,000 patients will develop this complication, but the mortality rate in those patients who do develop it is quite high (129). The consequences of many idiosyncratic drug reactions can be minimized if the reaction is identified early. Thus, prevention of serious complications from many drug reactions relies on prompt recognition and early intervention.

Factors Affecting Complication Rate and Severity

The frequency and severity of complications in patients receiving infusion therapy depends heavily on the clinical characteristics of the patient, the therapy given, and the clinical competence of the provider.

Of these factors, the patient's underlying condition is probably the most fundamentally important. Comorbid conditions that predispose individuals to complications significant.ly affect the outcome of patients treated with infusion therapy (131). An AIDS patient treated for bacterial pneumonia, for example, would be expected to be at a far greater risk for complications than would another pneumonia patient without the underlying problem of AIDS.

The specific diagnosis for which any particular drug infusion therapy is employed also influences its safety. For example, a patient treated for cellulitis with IV antibiotics can tolerate the complications associated with that therapy much better than a patient with meningitis treated with the same therapy; the patient with meningitis has an inherently less stable condition and is more at risk for poor outcome should any drug side effect occur. For this as well as many other reasons, the cellulitis patient might be treated at home, but the meningitis patient would remain in the hospital for therapy.

Some categories of therapeutics are inherently more risky than others. Antineoplastic drugs, for instance, are usually more toxic than are anti-infectives. Within each category, however, is a hierarchy of toxicities; some anti-infectives have the potential for more serious side effects than some antineoplastics. Amphotericin B, a drug used to treat severe fungal infections, for example, causes "potentially dangerous reactions in most patients" (11) and can be fatal if inadequately administered and monitored. In contrast, the side effects of leupride, a hormone used in the management of prostatic cancer, include bone pain, hot flashes, nausea, and impotence (11). Although these side effects are unquestionably unpleasant, they are far less potentially lethal than those seen with amphotericin B.

Similarly, the choice of vascular access device[8] can affect the types and rates of complications that arise. Central venous catheters, which lie near major vessels, nerves, and organs, have the potential to cause more severe consequences if infiltrated or inserted improperly than a standard peripheral IV catheter, and the long-term implantation and direct vascular access of central catheters makes them more susceptible to potentially dangerous infections (see ch. 3).

The provider also plays a major factor in the outcome of patients treated with infusion therapy. Adherence to published guidelines for the proper care of infusions and infusion devices reduces the frequency and severity of complications (311). Strict aseptic technique, regular changing of the site where a peripheral catheter is inserted, and careful attention to any early sign or symptom of an infusion-related complication is required of any home care provider (312). (The role of quality review to ensure the competency of providers is explored in chapter 5.)

Relative Risks: Home v. Hospital Drug Infusion Therapy

None of the complications of infusion therapy described above is setting-specific. The consequence of these problems, however, may differ depending on whether the therapy is given in the home or in a medical setting.

The degree of monitoring that occurs in the standard inpatient setting is usually greater than can occur in the home, because of the use of electronic monitoring in many patients and because nurses and physicians are on site. One tradeoff to home administration of infusion therapy, therefore, is a potentially higher frequency of unrecognized and/or untreated complications from the drugs themselves. Infection at the catheter site, for example, can potentially be recognized at an earlier stage by trained personnel in the hospital and be treated effectively by IV site rotation. The same catheter site infection may not be recognized as early at home and a more extensive infection may ensue.

Alternatively, there are certain complications that can actually be worse in the hospital setting than if they were encountered in the outpatient (or home) setting. Catheter site infections that occur in the outpatient setting, for example, are usually caused by organisms that are fairly susceptible to most antibiotics. Those acquired in the hospital, on the other hand, are usually caused by more aggressive, less sensitive organisms which can be more difficult to treat. In one survey of a hospital-based home infusion therapy program, nosocomial (hospital-acquired) infections were seen in approximately 14 percent of hospitalized patients compared with almost no infections in the patient group being treated as outpatients (15). Some of this difference is undoubtedly due to the presence of more stable patients in the outpatient group, but some is probably also due to the reduced exposure of outpatients to potentially significant nosocomial infections.

Any patient who is starting a new drug is at risk of experiencing an unpredictable allergic reaction or other drug-related complications. Thus, even when home infusion is otherwise feasible and safe, the first dose of any infused drug is usually administered under medical supervision, in the hospital, physician's office, or outpatient clinic, where personnel have access to needed resources should a dangerous reaction occur (15,131). Similarly, when the drug is changed during the course of home therapy (e.g., when a more sensitive antibiotic is substituted to achieve better therapeutic results), many providers believe the patient should return to a supervised setting for the initial dose (15).

Whether the elderly are, on average, at greater risk of infusion-related complications than younger patients is not entirely clear. One the one hand, elderly individuals are more likely to have other disabilities

[8] See chapter 3 for a discussion of venous access devices.

that may affect their health state, and they may be more likely to develop allergic reactions to a drug due to a greater chance of past exposure. On the other hand, there is no clear evidence that well-screened elderly patients on HDIT are at higher risk of complications. The single study in the literature on the topic found no difference in the therapeutic outcome of elderly and nonelderly patients treated with home IV antibiotic therapy when similar clinical and social inclusion criteria were used for both groups (65). It may be that fewer elderly than nonelderly patients would meet strict screening criteria, but that once those criteria are met the risks of HDIT in the two groups are comparable.

The Effectiveness and Use of HDIT

Reports on home use of a multitude of drug infusion therapies can be found in the literature. By far, the most common category of drugs is antibiotics and other anti-infectives. Based on estimates by market analysts and other sources, it appears that about two-thirds of current HDIT involve anti-infective drugs (34,193) (table 2-4). Approximately another 15 percent of HDIT drugs are antineoplastics or pain medications. The diverse remaining group of drugs makes up somewhere between 10 and 20 percent of HDIT at present. Although small and encompassing many unrelated drugs, this "other" group appears to be have grown rapidly (364).

Estimates based on drug orders and drug revenues may not reflect exactly the actual distribution of patients on different therapies. One investigator, for example, reports that antibiotics accounted for about two-thirds of drug orders but only about one-half of patients in his study (193a). A recent survey of the records of 35,000 patients served primarily by large infusion specialty companies likewise found that just over one-half (52 percent) of drug infusion patients were on antibiotics, another 21 percent were receiving either antineoplastics or pain medications, and over 5 percent were receiving more than one type of drug infusion therapy (256).

Antibiotics

Antibiotic and other anti-infective drugs constitute the bulk of HDIT for good reason. Their safety and efficacy when provided in nonhospital settings has been demonstrated in a number of studies (106,148,267,325). In virtually all of these studies, home patients achieved cure rates as good as or better than those attained in the inpatient setting.

Table 2-4-The Home Drug Infusion Market, 1989

Therapy	Total revenues: Millions of dollars	Total revenues: Percent of market
Antibiotic therapy	600.0	69.6
Pain management	91.1	10.6
Antineoplastic therapy	125.8	5.1
Other therapies	484.2	14.6
Total	1.301.1	100.0[a]

[a]Numbers do not add to exactly 100 due to rounding.

SOURCE: Adapted from Biomedical Business International, Santa Ana, CA, "Home Infusion Therapy Markets," 1989.

Table 2-5-Percentage of Intravenous Antibiotics Used in Home Treatment in Two States, 1989

Drug	North Carolina	Florida
Amphotericin	6.5	—
Cefazolin	3.2	16.7
Cefotetan	8.1	—
Ceftazidime	8.1	2.7
Ceftriaxone	25.8	11.1
Gentamicin	8.1	6.9
Tobramycin	3.2	8.3
Vancomycin	12.9	15.3
All other drugs	22.8	35.9

SOURCE: Adapted from C. Kozma and J. Glaze, "Impact of Home I.V. Benefits on Beneficiary Utilization of Services," interim paper prepared for Health Care Financing Administration, Baltimore, MD, Cooperative Agreement No. 17-C-9957/4-01, April 1990.

Home antibiotic therapy is reported to be effective in over 90 percent of cases (148,325).

The frequency with which a particular compound or class of compounds finds use in HDIT is related to the severity of associated complications. More aggressive and potentially complicated drugs are used less often.

Cefazolin and ceftriaxone, two members of a class of antibiotics known as cephalosporins, account for about half of all home IV antibiotics (table 2-5). Cephalosporins are relatively new antibiotics that share a number of characteristics that make them attractive for use in the home setting. In general, they are comparatively safe and act on a fairly broad spectrum of disease-causing organisms. Additionally, they require little monitoring and fairly infrequent administration. Ceftriaxone, for example, is usually administered only once or twice a day (11). Its infrequent administration makes it much more convenient for home use than penicillin, which has a similar spectrum of action but must be given much more frequently to be effective.

Unfortunately, ceftriaxone may not be particularly effective against *Staphylococcus aureus*, a

common organism that is frequently encountered in the kinds of infections seen in the home care setting (148,317). Other antibiotics, such as cefazolin and methicillin, appear to be more effective and can be used in the home to treat infections from this organism, although they require a more frequent dosing schedule (317).[9]

Another consideration in choosing a particular antibiotic for use in the home is the stability of the compound once the drug is mixed. Several antibiotics that are used extensively in hospitals, such as ampicillin and trimethoprim-sulfamethoxizole, have a very short period of stability when prepared for an IV infusion. Thus, they are rarely used in the home, where drugs and supplies are often delivered no more than once every week or two to minimize costs (3,317,364).

Complications

The incidence of complications arising from home IV antibiotic use is small. Although no drug is entirely safe, antibiotics, in general, are relatively safe and without significant adverse side effects when compared with other classes of drugs. Specific complication rates documented in published studies and in data provided to the Office of Technology Assessment (OTA) range from 6 to 20 percent (106,148,250,267). Almost none of the complications encountered were unique to the home setting but were inherent to IV therapy per se. A detailed record review performed by one HDIT provider found an IV-related complication rate of 10 percent (250) (table 2-6).

One complication unique to the home setting is an "antabuse" type of reaction[10] seen with certain cephalosporins. When a patient treated with these drugs also consumes alcoholic beverages, the combination can produce symptoms that include severe flushing, nausea and vomiting, chest pain, marked uneasiness, weakness, and confusion. Hospitalized patients do not usually consume alcohol and are not prone to developing this side effect. Patients at home, on the other hand, have free access to alcohol and thus have the potential for developing this drug interaction (106). The severity of the reaction is roughly proportional to the amount of alcohol ingested (11).

Table 2-6-Complications of Infusion Therapy Reported by One Home Infusion Provider

Complications presumed related to infusion therapy	
Catheter infection	
HIV[a] infection complication (resulting in immunosuppression)	
Diarrhea/dehydration	
Respiratory distress	
Increased wound infection symptoms	
Fever of unknown origin	
Central venous catheter replacement	
Sepsis	
Exacerbation of condition (possibly drug related)	
Bacteremia	
Proportion of all home infusion patients experiencing complication	10.1%

[a]HIV = human immunodeficiency virus.

SOURCE: H. O'Keiff, Barnes Home Health Agency, Inc., St. Louis, MO, letter to the Office of Technology Assessment, Feb. 28, 1991.

Antineoplastic Therapy

The goal of antineoplastic therapy is to selectively inhibit or destroy the rapidly dividing cells of a malignant tumor, while leaving the patient's normal cells intact. Different classes of antineoplastic drugs accomplish this goal in a variety of ways, with no single therapy universally applicable to all forms of cancer. Often, multiple antineoplastic agents are combined in a regimen to take advantage of the different modes of action while minimizing the varied toxicities.

Several trials and pilot studies have demonstrated the efficacy and safety of home IV antineoplastic therapy (116,201,263,294). In practice, a wide variety of agents are employed. One home infusion provider, for example, supplied seven different antineoplastics and related services to home patients in 1989 (250).[11]

Antineoplastic agents are frequently accompanied by serious side effects (table 2-7). The drugs find use despite these side effects because the underlying condition being treated has such a grim prognosis. Nonetheless, antineoplastic therapy presents a particular concern for safety in the home,

[9] There is not complete agreement on the relative effectiveness of these drugs; some physicians maintain that ceftriaxone maybe nearly as effective as cefazolin against this organism (340a).

[10] This reaction is identical to that seen in patients taking the drug disulfiram (Antabuse), a drug used as an adjunct to &w@ chronic alcoholism (129), and has, therefore, been termed the "antabuse reaction."

[11] The drugs were mitoxantrone, vinblastine, methotrexate, fluorouracil, doxorubicin, cyclophosphamide, and vincristine.

Table 2-7—Toxicity of Antineoplastic Drugs

	Major acute toxicity					Major delayed toxicity	
Drug	Chills/ fever	Diarrhea/ nausea/ vomiting	Local irritant/ local pain	Hypersensitivity reactions and anaphylaxis	Other[a]	Bone marrow depression	Other[a]
Asparaginase	X	X		X			X
Bleomycin	X	X		X			X
Carmustine		X	X			X	X
Cisplatin	X	X		X		X	X
Cyolosphosphamide		X				X	
Cytarabine, cytosine arabinoside	X			X		X	X
Dacarbazine		X	X			X	
Dactinomycin		X	X			X	X
Daunorubicin		X	X		X	X	X
Doxorubicin		X	X		X	X	X
Floxuridine (FUDR)		X				X	X
Fluorouracil (5-FU)		X				X	X
Mechlorethamine		X	X			X	
Methotrexate		X		X		X	X
Mitomycin		X	X			X	X
Plicamycin		X				X	X
Streptozocin/streptozotocin		X	X			X	X
Thioquanine		X				X	
Thiotepa		X	X			X	
Vinblastine		X	X			X	X
Vincristine			X			X	X

[a]"Other" acute toxicities include red urine, electrocardiogram changes, and orthostatic hypotension. "Other" delayed toxicities include such side effects as hair loss, liver and kidney damage, oral ulcers, stomatitis, neurological defects, and thrombocytopenia.

SOURCE: Based on T.M. Speight (cd.), Avery's *Drug* Treatment (Auckland, New Zealand: ADIS Press Ltd., 1987).

where both the ability to deal with the side effects and the system to dispose of the toxic drugs themselves are less available.

Many antineoplastic agents are *vesicants* and can cause severe irritation to the vein. When administered through a peripheral catheter, the incidence of thrombophlebitis is much higher than for most antibiotics and other nonvesicant drugs. To minimize the damage done to the vein, antineoplastic agents are frequently administered directly into a large, central vein to dilute the drug and diminish its toxicity. Table 2-8 lists some examples of IV antineoplastic agents and the requirements for administration.

Depending on the particular kind and location of the cancer, some antineoplastic drugs can be given directly into the artery that supplies it with blood. By delivering a more concentrated dose of a drug to the tumor, the potential for side effects can be minimized. Thus, intraarterially delivered antineoplastics produce fewer systemic side effects than they would if given intravenously. The tradeoff, in this instance, is the potential problems associated with intraarterial drug administration.

The advent of continuous infusion therapy has expanded the number and kinds of antineoplastic agents that may be delivered in the home setting (201,297). To achieve effective concentrations when given intermittently, a drug may need to be given at such high dosage that it causes serious side effects. As a continuous infusion, however, the concentration required for efficacy is often not as great and some adverse consequences can be avoided. Thus, the toxic effects of certain antineoplastic agents can be reduced by utilizing a longer exposure to a lower dose without losing any of the clinical efficacy.

The appropriateness of home antineoplastic therapy for a particular patient depends heavily on the underlying condition of that patient. Cancer patients are often weakened or incapacitated by the devastating effects of the disease and the therapies used to treat it. Unless these patients have sufficient in-home help in the form of a family member or other caregiver, home IV antineoplastic therapy is often not possible. Patients who are unwilling to learn the techniques, have an inadequate support system, or are physically unable to master the skills required thus represent poor risks for home IV therapy (35). Even if help and support are available, the tremendous demands frequently presented by cancer pa-

Table 2-8-Examples of Special Considerations in Administering Intravenous (IV) Antineoplastics

Drug	Special considerations
Asparaginase	Life-threatening anaphylaxis can occur. Skin testing and desensitization recommended before administration. During administration, a physician/life support equipment and epinephrine, antihistamine, and corticosteroids should be available; monitor blood pressure.
Bleomycin sulfate	Increased incidence of anaphyiaxis in lymphoma patients; give test dose. Give acetaminophen and antihistamine 30 min. before chemotherapy to prevent fever and chills.
Carmustine	Pain, burning at IV site and facial flushing may occur secondary to alcohol diluent; if this occurs decrease rate, increase volume in which drug is diluted.
Cisplatin	Before and during treatment, hydration and raised urinary output are essential to prevent nephotoxicity. Shorter infusion time may be associated with increased risk of kidney toxicity. Avoid the use of needles containing aluminum, as it reacts with Platinol to create a black precipitate and loss of potency. Anaphyiactic reactions may be controlled by epinephrine and corticosteroids.
Cyciophosphamide	To prevent hemorrhagic cystitis, patient should drink 3 to 4 liters of fluid per day and void frequently. Dizziness, rhinorrhea, sneezing and diaphoresis have been reported with doses of greater than 500 mg when given quickly.
Etoposide	Hypotension and wheezing may occur if given too rapidly (in less than 30 min.). Stop infusion if wheezing occurs; antihistamines may be helpfull.

SOURCE: Based on C.B. Hughes, "Giving Cancer Drugs IV: Some Guidelines," American *Journal of Nursing 86:34-38,* 1986.

tients can easily overwhelm the support system, requiring inpatient hospitalization.

Analgesics

Pain is a dominant feature of many disease conditions. Up to 70 percent of cancer patients suffer severe pain (401). Pain can usually be managed effectively with oral medication, but certain circumstances preclude this form of therapy. Patients with oral, esophageal, or other cancers which prevent normal swallowing, patients with breakthrough pain despite high doses of oral narcotics, and patients who suffer side effects related to the high doses of oral narcotics often required to control pain are candidates for parenteral analgesics (185).

Parenteral narcotic analgesics include meperidine, morphine, and hydromorphone. Their use in parenteral pain management varies widely; in one survey, the average duration of pain management therapy for different drugs ranged from 2 to 240 days (193). This variation probably reflects the relatively few patients on this therapy represented in the survey and the heterogeneous conditions for which pain control is used. IV narcotic pain relief has even been reported in a 2-year-old child being treated at home for advanced cancer of the brain (286).

While IV narcotic administration for pain control has been available for many years, the concept of home administration is fairly new. Two recent developments have been particularly important to enabling home parenteral pain control in many patients. First has been the development of infusion pumps with a patient-controlled analgesia feature. This feature allows patients to optimize pain relief but minimize drug side effects, by combining a constant preprogrammed baseline level of relief with the option to self-administer larger boluses of medicine when pain is particularly severe (265). Second, subcutaneous administration of narcotics has become a more accepted alternative that avoids some of the potential complications of IV therapy. In fact, subcutaneous pain management is considered by some to be superior to IV administration because of its equivalent effectiveness in many patients and its technical advantages (227).

Additionally, intrathecal and epidural administration of narcotics have been used for several years and are being increasingly considered as options for the home. A number of reports of parenteral pain management through one of these routes have been published (316,326,327), and HDIT providers report having provided them (250). However, intraspinal administration of narcotics is associated with complications including urinary retention, nausea and vomiting, and respiratory depression (202). Narcotic-induced respiratory depression, which is especially dangerous, can be detected by using an apnea monitor and can be counteracted by infusing an antagonistic agent (e.g., for morphine, Narcan is the antagonist) (202). Because respiratory complications may not present for up to 22 hours after epidural narcotics administration (309), these patients require extended monitoring and therefore can pose additional challenges for home care.

One concern unique to home parenteral narcotics administration is the potential for abuse of the drugs on the part of patients or family caregivers.[12] Providers of this therapy report such measures as hospitalizing patients with a history of IV drug abuse, rather than treating them at home, to minimize the opportunity for abuse; and discontinuing home therapy when it became apparent that a family member was diverting drugs intended for the patient (364). Special measures, such as using infusion pumps that enable the drug cassette to be locked and replaced only by a visiting nurse, may be required for home parenteral narcotic administration to be a safe option.

Other Therapies[13]

Dobutamine

Patients with congestive heart failure (CHF) suffer from an inability of the heart to pump a sufficient amount of blood to the vital organs. Dobutamine, which acts by increasing the force of contraction of the heart, has been used conventionally as a temporary measure in patients with underlying CHF whose heart needs assistance to deal with additional stress (e.g., an acute viral infection) (198). Dobutamine can only be administered intravenously, and until recently it was only administered in the hospital. In 1977, however, researchers discovered that 72-hour intermittent infusions of dobutamine improved cardiac function for prolonged periods (196). Subsequent studies confirmed these findings and furthered the idea that periodic outpatient administration of IV dobutamine may add to the treatment options for patients with CHF (205,348,349).

While the hemodynamic benefits of outpatient dobutamine are encouraging, the unexpected finding of increased mortality in these patients is not. One controlled study of the treatment found that despite significant improvement in symptoms during the study, 15 of 37 dobutamine patients (40 percent) died, while only 5 of 23 placebo-treated patients (22 percent) did so (94). The increased mortality was subsequently attributed to cardiac arrhythmias (irregular heartbeats). A recent study of an oral drug related to dobutamine likewise found that, despite the drug's predicted benefits, long-term therapy actually increased morbidity and mortality in patients with severe CHF (251).

Some researchers believe that many of the patients at risk of death during dobutamine treatment could be identified by means of pretreatment cardiac monitoring (322). The poor record of this and related drugs in existing studies, however, suggests that they do not merit long-term use in the home unless effectiveness in specific patient groups can be demonstrated.

One final argument favoring the use of IV dobutamine is that it may enable a patient with CHF who is a heart transplant candidate to survive until a suitable organ becomes available. Dobutamine is prescribed by some physicians for this purpose (73,365). Given the current evidence described above, this strategy may not really enhance a given individual's chance of receiving a transplant. Even if it does, it cannot increase the total number of people who ultimately can receive a new heart, because the number of heart transplants is limited by the supply of donor organs. The number of persons on the waiting list for heart transplants exceeds the number of transplants by about 30 percent (385a).

Immune Globulin

Human immune globulin was first used to treat patients whose bodies were naturally deficient in this substance in 1952 (52). Early administration consisted of periodic intramuscular injections (54). Intravenous preparations became available in the United States in 1981, and they are generally preferred for long-term therapy because they are less painful to receive and enable much larger doses to be given (54).

The clearest and most accepted indications for immune globulin therapy are for treating patients with severely impaired antibody-producing capacity (54). These patients may have any of a number of rare primary immunodeficiency diseases, such as severe combined immunodeficiency. Many of these conditions are chronic, and some individuals with

[12] "Family caregivers" are defined in this report as caregivers who are close friends or relatives of the patient and who generally receive no financial compensation for their services.

[13] In addition to the therapies described here, the list of drugs sometimes infused at home includes tocolytic drugs to prevent preterm labor (e.g., terbutaline and ritodrine); anticoagulant drugs (e.g., heparin); certain antiulcer drugs; and chelating drugs to rid the body of toxic levels of metals (e.g., deferoxamine).

them conditions require IV immune globulin therapy for life.

IV immune globulin is also sometimes used to bolster the immune systems of persons whose immunodeficiencies are secondary to another condition (e.g., those who have received immunosuppressive drugs in connection with their cancer treatment) (54,235). Recently, immune globulin has been shown to be effective in reducing the incidence of infections in children with AIDS (234) and in patients with chronic lymphocytic leukemia (77). The therapy is also gaining acceptance in treating other disorders that involve the immune system in some way, such as immune thrombocytopenic purpura, Kawasaki syndrome, and steroid-dependent asthma (323). Some have suggested that it may be successful in treating intractable seizure disorders, but it has not been tested for this use in a controlled study (235).

As IV immune globulin therapy has become used to treat a wide variety of diseases, questions have been raised about its cost. The charge for a single infusion of immune globulin has been reported anecdotally to be $125 to $250, making the annual charge for therapy for a typical adult requiring regular infusions over $25,000 for the drug alone (54). In some hospitals, immune globulin has become one of the top four drug expenditures (323). Some researchers have calculated the cost of prophylactic IV immune globulin for chronic lymphocytic leukemia to be $6 million for every quality-adjusted year of life gained (394).

The high cost of IV immune globulin therapy in the hospital, the fact that many patients are on therapy indefinitely, and the fact that many of these patients are children make home therapy attractive. A number of studies have shown that IV immune globulin therapy can indeed be provided safely in the home, with an effectiveness comparable to hospital therapy (17,190,191,247). Home use, however, will not reduce the costs of the drug itself.

Immune globulin therapy is not entirely free from the possibility of adverse events associated with the infusion of this substance. Mild reactions include nausea, fatigue, and headache; more serious reactions include severe chest pain, abnormal heartbeat, and mental confusion (122,235). These reactions can occur during or within minutes of treatment and may require immediate countermeasures (122). One recent study found that, of three methods of administering home immune globulin (intramuscular injection, IV infusion, or rapid subcutaneous infusion), rapid subcutaneous infusion resulted in the fewest adverse events while retaining its effectiveness (122). The results of this study, which was carried out in Sweden, suggest that more examination of subcutaneous administration in U.S. patients on long-term immune globulin therapy is warranted.

Blood Transfusions

The prototypical home transfusion patient is one who is anemic because of a chronic, debilitating condition, such as cancer or AIDS, and for whom transportation to a hospital or outpatient clinic would cause great difficulty (3,7,223,261). Anemia, by definition, is a reduction in the volume of red blood cells, and anemic patients usually have insufficient oxygen-carrying capacity in the blood (262). In addition to cancer- and AIDS-related anemias, certain other anemias (e.g., sickle-cell anemia) also may require transfusions of red blood cells[14] and might occasionally be treated in the home.

Individuals with thrombocytopenia (platelet deficiency), which impairs blood clotting at the site where a blood vessel is injured, may be candidates for home platelet transfusions. Thrombocytopenia can be caused by many different mechanisms, such as a bacterial infection or secondary to certain types of liver disease and bone marrow disorders (184).

Transfusion therapy poses certain risks unique to this form of infusion. It requires strict patient selection criteria and rigid transfusion procedures due to the potential severity of the body's reaction to foreign blood components.

The most serious reactions result from an incompatibility between antigens of the transfused blood component and the patient's antibodies. The consequence of this incompatibility is hemolysis, the vast destruction of red blood cells (7,184). Hemolysis can be fatal. Clinical symptoms include fever, chills, back pain, and possible shock. Proper followup and good patient records are imperative to ensure that donor and recipient blood are appropriately

14 Home blind transfusions virtually always involve transfusions of only certain extracted blood components. patients in need Of whole blood transfusions usually are those in need of urgent and intensive care (e.g., trauma patients) who are therefore unsuitable for home therapy.

matched; all home acute hemolytic reactions are due to clerical errors.

Febrile, non-hemolytic reactions are usually due to antibodies that cause clumping of the white blood cells that poison or destroy cells. Such a reaction usually occurs within the frost 1 or 2 hours of the transfusion. Characterized by chills and fever, non-hemolytic reactions usually can be treated successfully with aspirin or acetaminophen. However, a non-hemolytic reaction may signal a hemolytic reaction; symptoms must be considered potentially life-threatening until a hemolytic reaction can be ruled out (7,184).

Emerging Therapies

The broad acceptance of home drug infusion makes it likely that new and future drugs that must be given parenterally may find application in the home. Following are some examples of drugs that have recently begun to be used in this setting, or which might be provided in this setting in the future.

- *Granulocyte colony stimulating factor(G-CSF)* —A bioengineered version of a natural substance that regulates the growth and development of certain white blood cells, G-CSF has recently been approved by the FDA for use in cancer patients with low white blood cells counts and fever (15 1). Because it is a protein and subject to degradation by digestive enzymes, G-CSF must be administered parenterally (either IV or subcutaneously). It is administered as a daily injection for up to 2 weeks in conjunction with the patient's antineoplastic therapy cycle (14a). Because many patients are now receiving their antineoplastic therapy at home, G-CSF is also sometimes administered concomitantly at home (176).
- *Granulocyte microphage-colony stimulating factor* (GM-CSF)-Closely related to G-CSF, GM-CSF plays a similar biological role in acting to raise the white blood cell count. It also has been recently approved by the FDA for use in patients with Hodgkin's **disease, rlOrl-**Hodgkin>s lymphoma, and acute lymphoblastic leukemia who undergo bone marrow transplant (151). GM-CSF must be administered parentedally and may be used in the home by post-transplant patients. In addition, it has possible uses in cancer and AIDS patients who are at risk of infections (302).
- *Post-transplant immunosuppressive drugs*— Transplant recipients must usually take drugs that suppress their immune systems, preventing the body from rejecting the grafted organ. Most drugs currently used for long-term post-transplant immunosuppression are oral drugs such as cyclosporine. One FDA-approved drug, however-Orthoclone OKT-3—is an IV drug. Although its prophylactic use thus far has taken place while the patient is still hospitalized after the transplant (91), this and any future parenteral immunosuppressives might move home as part of strategies to reduce the hospital stays of transplant patients.
- *Interleukin-2-Still* under development, interleukin-2 holds promise as a future treatment for kidney cancer (282). The drug is not yet approved by the FDA for use in the United States, but its mode of administration (subcutaneous or IV) and the long-term nature of the disease it treats make it a likely candidate for home therapy if it should receive marketing approval.

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Chapter 3

HOME DRUG INFUSION THERAPY EQUIPMENT AND SERVICES

Overview

Introduction

The home infusion therapy industry today is the product of technological and medical advancements achieved primarily during the past two decades, and it is still evolving in response to continuing changes in both these areas. Twenty years ago, home drug infusion therapy (HDIT) without round-the-clock nursing services would have been unthinkable. Today, programmable infusion devices with built-in safety mechanisms and safer, more comfortable vascular access devices that can remain in place for longer periods of time have enabled even bedridden patients on complex therapeutic regimens to go home.

Skills as well as equipment have advanced, and many nurses and pharmacists now specialize in the particular professional skills needed in HDIT (e.g., placement of a peripherally inserted central catheter, drug regimen review). But not all HDIT techniques demand such a high level of skill. Some (e.g., simple wound care, drug administration) can be performed by trained family caregivers[1] or by patients themselves. This chapter describes the variety of equipment and supplies used, the broad range of techniques and services involved, and the skilled and nonskilled caregivers who provide HDIT in the 1990s.

Summary of Conclusions

- The services and supplies needed for HDIT vary significantly depending on the route of administration, type of vascular access device, type of therapy, and rate of administration. For example, patients with peripheral venous access require more ongoing skilled nursing visits than patients with central venous access. Patients with central access, however, may need more intense training, more early supervisory visits, and more phone support until they become comfortable caring for their catheter and administering their medication. Patients who self-administer antibiotics three times a day may require 20 times as many intravenous (IV) administration supplies as patients on continuous-infusion antineoplastic therapy or pain management.
- Although infusion devices have become increasingly sophisticated during the last decade, less expensive gravity drip systems are still safe and appropriate for many therapies. Most antibiotic therapy and hydration therapy can be delivered via gravity drip or special disposable infusion devices, provided patients (or their caregivers) are capable of operating these devices. In-home gravity drip systems often include special devices that enhance safety and ease of operation by patients. Factors that may necessitate the use of programmable infusion pumps include: cognitive or functional limitations of patients/caregivers; extremely high or low dose volume; therapies of long or otherwise inconvenient duration; therapies requiring frequent administration; intraarterial infusions; and need for carefully controlled rate of administration.
- While some of the specific techniques used in HDIT require the skills of specially trained registered nurses (RNs), many tasks can be performed by the patient or by a family member who has been taught the proper techniques by a qualified health professional. However, because Medicare beneficiaries are likely to be sicker than other patients and they and their spouses are more likely to have functional limitations than younger patients, they are more likely to need paid assistive services in order to receive infusion therapy at home. If the frequency and intensity of professional services required by a home infusion patient are great (e.g., a functionally disabled patient on a 4-dose per day antibiotic regimen who has no informal caregiver available), a skilled nursing facility (SNF) or other nonhospital institutional setting that offers 24-hour supervision might be a more reasonable alternative to hospitalization than traditional home care.
- Within the nursing and pharmacy professions, home infusion specialization is based primarily

[1] In this report, the term "family caregiver" refers to a friend or family member who assists an HDIT patient in self-care tales on a nonpaid basis.

on experience and has not yet achieved separate recognition by professional organizations. Increasing availability of formal training in infusion therapy techniques, however, is expanding the pool of qualified personnel. Although HDIT providers may occasionally have difficulty recruiting qualified staff, available evidence does not suggest a critical shortage of qualified personnel.

- The continual emergence of new HDIT technologies constantly broadens the types of patients who can be treated at home and changes the parameters of service delivery. Each new device involves the use of new techniques that must be learned by nurses, pharmacists, and patients and caregivers. Some recently developed technologies have reduced the amount of skilled nursing intervention required for patients at home and made it easier for patients to self-administer complex drug regimens.

Equipment

The two fundamental items of equipment used in HDIT are the vascular access device[2] (the path through which a drug enters the bloodstream) and the infusion device (the means of controlling the rate of an infusion). Advances in vascular access and infusion technology during the past two decades are what have made HDIT possible, and the range of patients who can receive therapy at home continues to expand as new technologies emerge.

Vascular Access Devices

Twenty years ago, the most common mode of parenteral administration was a steel needle inserted into a vein in the hand or arm (peripheral vein). Today, an increasingly broad array of vascular access devices is available, ranging from peripheral catheters (thin tubes inserted into a hand or forearm vein) to totally implantable catheters that access the centralmost vein of the body. The type of vascular access device used in HDIT has implications for both the amount of skilled nursing intervention required and the nature and extent of certain therapy-related risks for infusion patients.

The choice of a vascular access device depends on the drug(s) to be infused, the route of administration, the duration of therapy, and the physical condition of the patient. Data from a recent survey of specialty HDIT providers show that peripheral catheters are used most frequently for antibiotic therapy, while central catheters are more common for antineoplastic therapy, pain management, and patients on multiple therapies (256). Most vascular access devices can be used for more than one route of administration. For example, tunneled catheters and subcutaneous ports (see below) can be used for intravenous, intraarterial, epidural, intrathecal, or intraperitoneal administration; and peripheral catheters can be used for intravenous or intraarterial therapy.

Peripheral Catheters

Many drugs (e.g., most antibiotics) can be infused into a vein in the arm by way of a small catheter inserted into the blood vessel. Peripheral catheters are particularly appropriate in patients who require relatively short-term therapy (e.g., 1 to 3 weeks) and whose veins are healthy and can withstand repeated punctures (145). Maintenance of peripheral routes of administration requires frequent skilled nursing intervention. Although able-bodied patients can often manage the dressing changes (periodic replacement of bandages covering the catheter exit site) with the assistance of family caregivers,[3] catheter insertion requires professional skills.

Peripheral catheters must be changed frequently to prevent swelling and irritation at the entry site that can lead to infection. When this is done, the old catheter is discarded and a new one inserted, usually at a different site in the vein. Catheter change must be performed by a nurse or physician skilled in peripheral catheter insertion technique (174). Although the Intravenous Nurses Society (INS) standards of practice recommend that peripheral venous sites be changed every 48 hours (174), recent studies suggest that, barring other complications, peripheral venous catheters can often remain in place for up to 72 hours (206). The 72-hour rotation schedule has been widely adopted by HDIT providers (364). For peripheral arterial catheters, the INS recommends

[2] Many observers would categorize vascular access devices as "supplies," since they are generally intended for one-time use, but they are considered equipment hem to distinguish them from the routine disposable HDIT supplies discussed later.

[3] Assistance maybe required for dressing changes on peripheral catheters because the exit site is typically on the lower arm, precluding the use of one of the patient's hands.

less frequent site rotation (every 96 hours) due to the more limited number of arterial access sites (174).

Certain factors may necessitate more frequent site rotation for peripheral catheters. For example, a patient receiving a particularly irritating drug may experience painful swelling at the catheter site after only a small number of doses (390). Some elderly patients with poor venous access may experience more rapid site deterioration than younger, healthier patients (364).

Most peripheral catheters today are made of rigid Teflon™ rather than steel. The rigidity of the material sometimes contributes to mechanical phlebitis, an inflammation caused by irritation of the surrounding tissues (154). Some newer peripheral catheters are made of a polymer that expands to the required diameter after it is in the vein, making insertion less painful (141). The reported increased comfort and lower risk of complications associated with these catheters may reduce the frequency with which they must be replaced (84,154,330).

This new technology highlights the difficulty of adjusting protocols quickly to reflect new products and techniques. Some home infusion companies are hesitant to use the new catheters; others use them but replace them at the recommended intervals for Teflon™ catheters; and at least one large home infusion company reportedly has protocols that allow the new catheters to be left in place for up to 14 days if there are no complications (84,141).4

For HDIT patients, it is generally the nurse who is responsible for deciding when peripheral catheters should be changed. The decision to leave a catheter in place for a longer or shorter period than the recommended standard is based on an assessment that includes consideration of the condition of the current catheter site, availability of new sites, condition of the patient's skin, type of drug, and expected duration of therapy (141).

Central Catheters

Drugs that are potentially toxic or irritating to a vein must be introduced into a large volume of blood, to dilute the drug and reduce the likelihood of blood vessel damage. These drugs are delivered by way of a catheter whose tip rests in a large central vein such as the subclavian vein or the superior vena cava (which feeds directly into the heart). Central catheters require especially meticulous care by the patient or caregiver to prevent infection at the open site where the catheter enters the body, but they usually require less frequent skilled nursing intervention than peripheral catheters. Routine site changes are not necessary with central catheters, and patients can use both hands for catheter care procedures. Another advantage of central over peripheral catheters is that patients are spared the discomfort of repeated venipuncture, because central catheters can remain in place much longer (145). The implantation of a traditional central catheter is a minor hospital surgical procedure that must be performed by a physician (161). Placement of the tip of the catheter must be confirmed by x-ray.

Central catheters may be appropriate not only for drugs requiring greater dilution, but for long-term infusions of other drugs, for patients needing infusions of multiple drugs,[5] for patients likely to need repeated episodes of infusion, and for patients with peripheral veins unsuitable for repeated puncture (140,145).

The two traditional types of central catheters are:

- *Nontunneledcatheters (e.g.*, Hohn, subclavian), which are inserted through an opening in the neck or shoulder directly into the vasculature (blood system). The tip of the catheter rests in a large vein near the heart-either the subclavian vein or the superior vena cava.
- *Tunneled catheters (e.g.*, Corcath, Hickman, Broviac), which are inserted into the chest wall and are tunneled through the skin several inches before entering the vasculature.

Tunneled catheters are used commonly in home patients because they are associated with a lower risk of infection and are easier to care for (260).

A relatively recent addition to the menu of catheter choices is the peripherally inserted central catheter (PICC line), which is being used increasingly in the home setting (50). The PICC line is an alternative to both surgically placed central catheters and traditional peripheral venous access. In this

[4] The use of these new catheters has not yet been reflected in recognized standards of practice, which still state that peripheral lines should be changed every 48 hours (174).

[5] Central catheters come in single- or multiple-lumen styles. Each lumen is a separate path through which a drug can be administered. Multiple-lumen catheters facilitate multiple infusions and, in some cases, allow for continuous venous pressure monitoring during and between therapy (264).

case, a long catheter is inserted into a small vein, usually in the forearm, and threaded up the vein toward the heart (50). The catheter is anchored with a suture or special tape at the exit site in the arm; like the exit site of a surgically placed central catheter, this site requires meticulous care to prevent infection (140,145). Unlike other modes of central venous access, placement of the PICC line does not necessarily have to be performed by a physician; in most States, specially trained nurses can insert it. Because the specific point of placement of a PICC line is crucial, proper placement should be confirmed by x-ray (50,174).

PICC lines are sometimes favored over traditional peripheral catheters because they allow for greater dilution of the drug and do not have to be changed as often. Complications of PICC line insertion can include tendon or nerve damage, bleeding, cardiac arrhythmias, chest pain, respiratory distress, catheter embolism, and malposition of the catheter (50). However, many consider these complications to be fewer and less severe than those associated with traditional central catheter implantation and use (50). Furthermore, the risk of an air embolism (see ch. 2) is decreased because the line is maintained below the heart.

The quality and safety of PICC line use in the home setting depends on the skill of the health professional who inserts and maintains the device PICC. Safety also depends on the ability of the health professional, patient, and/or caregiver to properly care for the PICC line and recognize related complications.

For some medications, the peripherally inserted catheter need only be threaded up to the large vein in the upper arm to achieve adequate dilution. When this method of placement is used, the catheter is referred to as "midline' and radioscopic confirmation of placement is not usually necessary (50). As with the PICC line, midline insertion can be performed either by a physician or (in most States) a nurse specialist at the patient's bedside (174). Although midline catheters allow for greater dilution of the drug than traditional peripheral catheters and are frequently left in place for considerably longer periods of time (141), they are still considered peripheral lines by the INS for purposes of maintenance and replacement (i.e., INS recommends replacement every 48 to 72 hours) (174).

PICC lines and midline catheters are made of one of three materials: polyurethane, which is rigid but softens once in the vein; silicone elastomer, which is very soft and must be inserted through a needle or another Teflon™ catheter; and elastomeric hydrogel, which is rigid but both softens and expands once in the vein (140).

Totally Implantable Catheters

Because they exit through an opening in the skin, all of the above types of central catheters are accompanied by the risk of infusion-related phlebitis and infection. To reduce these risks, totally implantable catheters were developed for patients on long-term infusion therapy (396).

Totally implantable catheters, also known as subcutaneous ports, consist of a small reservoir that is surgically implanted under the skin and tunneled to a catheter. The catheter itself may lead to a central vein, a large artery, or into the intrathecal or epidural space (174). The side of the port facing the skin consists of a self-sealing septum. The port is accessed by a special needle designed for this purpose which is inserted through the patient's skin into the septum. If desired, the needle can remain in place up to 7 days at a time, at which point it is changed by the patient or a nurse to minimize the risk of contamination (174). The drug is infused through the needle into the port and thence into the catheter (80,145).

Like other central catheters, subcutaneous ports are appropriate for patients on long-term therapies and those for whom peripheral infusion is unsuitable (145). One disadvantage is that the patient's skin must be punctured at least once a week. Also, although the need for surgical replacement due to catheter site infection is reduced, the port itself must be replaced approximately every 2,000 punctures (about once every 5 years if punctured once a day) (145).

Access Devices for Other Modes of Drug Delivery

For patients with relatively short-term needs for infusion, or who for some reason are unsuitable for alternative modes of access, some drugs may be infused by way of a needle that is simply inserted under the skin. Subcutaneous infusion is limited to drugs that require administration of a relatively low volume of fluid over any given period of time (see ch. 2). Narcotics to manage pain in patients with advanced cancer, for example, can be administered

by continuous subcutaneous infusion. When infusion is continuous, needles should be changed every 48 hours (174).

Narcotics to manage pain may also be delivered directly into the epidural or intrathecal spaces surrounding the spinal cord. In either case, a catheter is inserted between the vertebrae and threaded several inches up along the spinal cord in a minor surgical procedure (326). The procedure is performed by a physician and may be done in the hospital or in an ambulatory surgical setting. As with central venous catheters, epidural and intrathecal catheters may be connected to a subcutaneous port or tunneled under the skin to an exit on the side of the body. Patients with intrathecal catheters intended for long-term use may have the catheter connected to a implanted infusion pump, requiring no external apparatus at home at all and greatly reducing the risk of infection (326).

For a given HDIT provider, the proportion of patients with a particular type of vascular access device is a function of both patient needs and characteristics and the provider's preference for and expertise in the use of certain devices. For example, providers who serve pimarily terminal cancer and parenteral nutrition patients may use surgically implanted central catheters almost exclusively, while providers of shorter-term antibiotic therapies may use peripheral catheters more frequently (364). PICC lines have become the device of choice for some providers, while others do not use them because their staff are not trained in PICC line insertion and maintenance (364).

Infusion Devices

Any drug infusion requires some kind of device that controls the rate at which the drug enters the body. Infusion devices used in home therapy today range from simple gravity drip systems to highly sophisticated programmable electronic pumps. The choice of an infusion device depends on both therapy and patient characteristics. Some IV therapies can be delivered safely and effectively through gravity drip systems, while others require the increased control, positive pressure, and greater flow rate range offered by electronic pumps.

Gravity Drip Systems

The simplest infusion device is the "gravity drip": the bag or bottle is hung on a hook or pole above the level of the patient, and fluid flows by gravity down the line and into the catheter. The rate of flow in a simple gravity drip system is controlled primarily by a special clamp or valve on the line that can be manually adjusted to permit the prescribed amount of fluid to flow through (usually described in drops per minute). These devices range in complexity and ease of operation from roller and slide clamps to more sophisticated rotating valves. Compared with slide and roller clamps, rotating valves are less awkward to manipulate and provide a more consistent flow rate (264). Even the most sophisticated manual drip valve, however, cannot offer precise flow control, because the viscosity of the solution being infused (the *infusate)* affects the volume of each drop and hence the rate of flow (264). The size of the needle at the end of the line, through which the fluid flows into the catheter, offers a second flow control; the smaller the needle, the slower the maximum rate of flow into the body.

Controllers can provide an added measure of security against uneven or "runaway' flow of infusate in a gravity drip system (264). These electronic devices use a drop sensor to monitor flow rate and can detect infiltrations and malpositioning of the catheter or IV tubing by measuring backflow. An alarm sounds when flow rate is altered or when backflow is detected (264).

The gravity drip is conceptually simple, cheap, and requires less equipment than most other infusion systems. In the home setting, however, it has some limitations. First, it is difficult to maintain a constant infusion rate in a gravity drip system due to factors such as the decreasing volume of fluid in the bag (i.e., the infusion rate will decrease as the bag empties) and changes in the shape of the tubing around the clamp (264). Consequently, a gravity system may provide insufficient flow control for drugs that require a very slow, very precise, or very long infusion time, such as antineoplastic (103). Second, errors in using the gravity drip that remain unnoticed can result in serious complications. For example, if the clamp malfunctions or the flow rate is improperly set, a drug may flow virtually unrestricted into the body, giving rise to severe adverse drug reactions and other complications.

In addition, a gravity drip system may be an inappropriate choice for certain patients due to functional limitations of the patients or their caregivers. Because the IV bag is suspended well above the catheter site in this system, patients with decreased mobility may have difficulty changing the bag. Ambulatory patients on continuous infusion may also find gravity drip frustrating because the system is not easily portable.

Despite the drawbacks of this traditional method of IV administration, it does maintain some important fuctional advantages over more the expensive electronic infusion devices discussed below. Because the drugs are forced into the vein under the pressure of gravity alone, there maybe less irritation at the catheter site, especially peripheral catheter sites (390). Gravity drip systems may also be preferred for patients who are confused by and resistant to learning how to use more complex, computerized drug delivery systems.

Infusion Pumps

The availability of an electronically controlled device that could deliver constant and precise amounts of fluid over time was a major technological advance in infusion therapy. Although many therapies can be delivered safely and effectively via gravity drip systems, others require the highly precise and constant flow rate offered by electronic infusion devices (103). For example, intraarterial infusions usually require positive pressure pumps because the back pressure is higher in arteries than in veins (397).

Most infusion pumps work by peristaltic action—i.e., by alternately squeezing and releasing the tube containing the fluid to force the fluid through at a predetermined rate. A second type of pump uses a syringe-type pushing action to force the drug down the tubing. Most infusion pumps used in HDIT are modern, sophisticated versions of one of these two types of pumps (103).

With the advent of home infusion therapies in the 1980s has come the development of small, portable pumps with specialized uses for particular types of therapies and adaptations for use by nonprofessionals. Because computerized pumps can deliver medication at a wide range of dose frequencies and intensities, they broaden the scope of therapies that can be safely and effectively administered at home. Pumps specifically for the infusion of narcotics to treat cancer-related pain, for example, may have adaptations that provide a low level of ongoing infusion but also permit patients to dose themselves with bursts of medication when pain becomes intense, up to a preprogrammed number of such extra doses per day (215). Other pumps, designed for the volume of fluid typical of most antibiotic therapy, can be preprogrammed to deliver infusions at standard intervals (e.g., 4 times per day), thus enabling patients to sleep undisturbed while receiving therapy (215). Pumps used for long-term IV nutrition administration, on the other hand, may be designed to administer the large volume of fluid required for the overnight infusions typical of patients receiving this therapy (103,283). One syringe-type pump permits the simultaneous administration of several different therapies at different intervals, with dosages and administration regimens preprogrammed on a microchip which fits in the back of the pump (86).

Pumps currently available for home use range in complexity and sophistication from very simple, single-medication stationary infusion pumps to fully programmable, ambulatory pumps that can deliver multiple medications and are equipped with a variety of alarms, bells, and other 'failsafe' mechanisms (103). While stationary pumps may be appropriate for patients who are bedridden or whose medications are delivered over shorter periods of time, ambulatory pumps provide greater independence for patients on continuous, frequent, or long-term therapy regimens. For example, ambulatory pumps enable patients to receive antineoplastic therapy continuously while engaging in normal daily tasks. Many pumps also have automatic "piggyback" mechanisms that control secondary infusions at an independent rate, decreasing the nursing time required for multiple infusions (103).

Infusion pumps do have certain disadvantages. If patients, caregivers, or even health professionals find the level of sophistication of these pumps confusing, the patients' safety could be jeopardized through misuse of equipment (103). Many patients, and the nurses who instruct and care for them, might prefer simpler models that are easier to operate. Even many hospital nurses are unfamiliar with or unaware of sophisticated features of pumps they use on a regular basis (103). Highly sophisticated pumps cost more and often require considerably more training for both the health professional and the patient than simpler models (283).

New types of electronic infusion pumps are constantly evolving, widening the menu from which providers must choose and which patients and health professionals must learn to operate. For example, one recently developed pump uses a built-in scanner to self-program, based on a bar code on the bag of infusate, thereby eliminating the extra step of manually programming the pump (40). Another device currently under development is a watch-sized delivery system for low-volume therapies such as pain management and antineoplastics (228).[6]

Elastomeric Infusers

Elastomeric infusers are recently developed devices that can be used as substitutes for infusion pumps. These infusers consist of disposable containers with inner elastic bladders that can be filled with the medication. The devices are sold empty and are filled by the pharmacist through a port at the top of the bladder (28,29,40). The drug flows through an opening at the base of the bladder membrane and into the tube leading to the patient. The force of the flow, and thus the rate of infusion, is determined by the elasticity of the bladder (which pushes inward, delivering the drug under positive pressure) and the concentration of the drug in the infusate, regardless of whether the bladder is above, below, or on level with the IV site (28,29,40). Different drugs and dosages require devices of differing size and bladder membrane composition.

Most devices currently on the market are designed for either antibiotic or antineoplalstic therapy administration. They can be used for IV, intraarterial, and subcutaneous administration of drugs (28). A patient on a twice-a-day regimen of home IV antibiotics would use two infusers per day, while a patient on continuous antineoplastic therapy might use a single device for several days at a time (28). Some devices allow patient-controlled administration of bolus doses above and beyond the continuous infusion rate. A disadvantage to the use of these devices for patient-controlled analgesia is the lack of a memory function that can record the frequency of patient-requested bolus doses, like that found in some electronic infusion pumps (see above). Bladder devices are also not appropriate for multiple drug regimens.

According to one home infusion provider, the availability of disposable elastomeric infusion devices has increased the feasibility of home-based care for disabled elderly patients (249). Like sophisticated electronic infusion pumps, these devices can deliver a precise dose over a specific period of time. However, because they are self-contained and much simpler to operate, they may be less confusing for patients who are uncomfortable with high-tech equipment. The patient or caregiver need only hook the device to the catheter at dosing time and disconnect and dispose of it when the dose has been completed.

Implantable Pumps

Some therapies that require very small drug dosages can be administered by way of totally implantable pumps. Examples include insulin delivery, continuous epidural morphine administration for chronic pain management, and continuous venous antineoplastic therapy infusion for liver cancer patients (the catheter is threaded into the portal vein leading to the liver). Due to the limited range of conditions for which they are currently used and the much lower intensity of services required, however, they are not discussed further in this report. The only service directly related to infusion therapy for these devices is refilling of the pump's reservoir, which may be done weekly or even less frequently in a medical outpatient or home setting (260).

Techniques and Supplies

The supplies and skills needed for HDIT depend on the type of therapy being administered, the vascular access device, and the infusion device. This section describes procedures associated with the use of different types of home infusion equipment and the supplies required for those procedures.

Some supplies are needed by nearly all patients on HDIT, although specific amounts vary depending on the patient (table 3-l). Examples of general HDIT supplies include such items as special soaps, swabs, catheter clamps, and sterile gloves.

Other supplies relate to specific HDIT procedures (table 3-1).[7] A patient receiving antineoplastic therapy, for example, needs special containers to

[6] The system includes a miniature programmable pump that operates electrolytically rather than by peristaltic or syringe-pump action. A weak electric current causes gas in a tiny reservoir to expand, thereby expelling the drug from a neighboring chamber into the catheter (228).

[7] The specific supplies listed in the table reflect the practice of this particular infusion company. Other providers may use different supplies.

Table 3-I—Typical Supplies[a] in a Delivery by One Company for Four Types of Home Infusion Therapy

Supplies[a]	Type of therapy: Central catheter — Pain management[b] (1 dose/5 days)	Central catheter — Continuous infusion antineoplastic therapy[b] (1 dose/5 days)	Peripheral catheter — Antibiotic therapy (2 doses/day)	Peripheral catheter — Hydration therapy[b] (1 dose/day)
Drug administration				
Intravenous (IV) pump (monthly rental)	1	1		
Pump cassette (100 ml) (5-day)	7	7	—	—
Battery, 9V[c]	4	4	—	—
Disposable elastomeric pump	—	—	56	
Gravity drip flow regulator (disposable)	—	—		28
IV pole	—	—	—	1
IV administration set, 96 inch	—	7	—	28
IV administration set, 66 inch	—	7		
IV in-line filter set, 1.2 micron	—	—		
Extension set, 6 inch	—	—	—	
Extension set, 30 inch	7	—	—	—
Extension set, 36 inch	7	—	—	—
Catheter clamp	2	2		
Peripheral catheter kit[d]	—	—	4	
IV catheter, 22 gauge[e]	—	—	—	4
Click lock needles	8	8	—	
Needles, 21 gauge X 1	—	—	56	28
Catheter/site care				
Alcohol preps (box)	1	1	1	1
Iodine preps (box) (central line only)	1	1	—	—
Antiseptic hand cleanser, 8 oz. bottle	1	1	1	1
Sterile gloves	8	8	56	28
Antiseptic table wipes (for work area)	7	7	56	28
Disposable sterile work surface	7	7	56	28
Dressing change kit (central line only)	12	12	—	—
Tegaderm dressing medication	12	12	9 to 12	9 to 12
Tape, plastic 1 inch wide (roll)	1	1	1	1
SASH kits (for catheter flushing)[f]	7	7	56	28
Injection caps, click lock	12	12	9 to 12	9 to 12
Other				
10 cc syringe with needle (for drawing blood)	4	4	4	4
Sharps container/disposal	1	1	2	1
Anaphylaxis kit	1	1	1	
Chemo spill emergency kit[g]		1		—
Chemo waste bag	—	2		—
Chemo protection kit[h]	—	1		

[a]Supplies may vary depending on individual patient characteristics and needs. Does not include drugs or therapeutics.
[b]Supplies listed are for a *1-month* regimen of the following therapies: *pain management*—morphine sulfate approximately 100 mg dose daily; *antibiotic*—Cefobid 1 g twice daily; *hydration*—dextrose 0.45 percent in 1 liter saline once daily; *chemotherapy*—fluorouracil 2500 mg/50 ml every 5 days continuous infusion.
[c]The antineoplastic therapy and pain management pumps need 9-volt batteries for backup power.
[d]Includes all supplies required to do three IV restarts (catheter, SASH kit, needles, etc.). These are usually performed every 3 days, although antibiotic patients may require more frequent restarts due to irritation.
[e]For hydration therapy, the full peripheral catheter kit is not required.
[f]SASH = saline-administration-saline-heparin. These are prepackaged kits used for periodic flushing of catheters. Some infusion therapy providers choose to use heparin alone rather than a SASH kit (see box 3-B).
[g]Includes special towels, goggles, warning signs, etc. in the event of a spill.
[h]Used by nurse, patient, or other caregiver who administers antineoplastic therapy.

SOURCE: S. Wyremski, Abel Health Management Services, Inc., Great Neck, NY, personal communications, Jan. 18 and 22, 1991.

ensure that the wastes associated with the therapy are suitably disposed of. A patient with a small, ambulatory pump may not require an IV pole to hang the pump, but he or she may need the special drug-containing pump cassettes. A patient on a 2-dose-per-day course of antibiotics needs 14 times as many dose administration supplies as a patient with a 7-day cassette for continuous antineoplastic therapy. A patient with a subcutaneous port requires specially designed needles that do not puncture the base of the port.

Most supplies fall into two categories: those used to prevent infection, and those needed to actually

Box 3-A—Aseptic Technique

To minimize the risk of infectious contamination in home infusion therapy, aseptic technique must be used each time the catheter site is exposed or the catheter or tubing is accessed. Examples include dressing changes, IV administration set changes, drug administration, and catheter care procedures (e.g., catheter flushing). The aseptic technique requires:

. *A clean, disinfected work area* (disposable sterile work surfaces can be used for extra protection).
- Meticulous handwashing with a disinfect soap before performing *any* home infusion therapy procedure.
- *Care in handling syringes so the* hands do not come in contact with the sterile needle or the lower part of the syringe plunger.

. *Care in use of needles.* When needles are used to access catheters or administration sets via external or subcutaneous injection ports, or are inserted directly into the skin for subcutaneous infusions, they must be fully engaged up to the hub and taped securely to the patient to prevent in-and-out motion of the needle from introducing bacteria into the vascular system.

* *Disinfection and cleaning of injection ports (if they are used) prior to access with a needle.*

. *Use of sterile gloves for catheter site care and dressing change.*

. *Metculous care of the catheter site, which should be cleaned three times in an outward circular motion with an* alcohol swab, using a new swab each time, and then with three providone-iodine swabs in the same pattern. Sterile gauze can be used to gently pat the site dry. After applying the new dressing, catheter tubing should be resecured with tape to prevent motion.

SOURCES: A.L. Plumer, "Bacterial, Fungal, and Particulate Contamination," in *Principles and Practice of Intravenous Therapy, 4th Ed.*, A.L. Plumer and F. Cosentino (eds.) (New York, NY: Little, Brown and Co., 198'7); National Medical Care, Inc., Homecare Division, *Central Line Catheter Care: Patient Information Guide* (Waltham, *MA:* National Medical Care, Inc., 1989).

administer the drug. These are discussed in more detail below.[8]

Infection Control

The three main sources of microbial (bacterial and fungal) contamination that can cause infusion-related infection are the skin, the air, and the blood (264). Although risk of infusion-related infection can be reduced by minimizing exposure of the catheter site, the administration set, and the container of infusate to these sources, exposure cannot be eliminated. To further reduce the risk of contamination, additional steps must be taken.

The most important method of controlling the risk of infection, whether at home or in the hospital, is the aseptic technique (see box 3-A). This technique must be applied to all procedures that involve exposure of any part of the infusion administration assembly (catheter site, catheter lock, tubing, etc.) or of any infused substances to the environment (264). These procedures include drug compounding and mixing, drug administration, peripheral site changes, catheter flushing, dressing changes, and administration set changes (see below). Strict adherence to the aseptic technique requires ample backup supplies, because if a piece of sterile equipment (e.g., administration set tubing, catheter cap, injection port, syringe plunger) is accidentally contaminated it must be discarded and replaced with a new one.

Another factor that can increase the risk of infusion-related infection is the use of multiple-dose vials of drugs for home administration. Because multiple-dose vials must be accessed repeatedly, they increase the risk of contamination from environmental sources. They may also be more susceptible to tampering by patients or other individuals who handle them (207). To minimize the risk of infection and tampering, some hospitals and home infusion companies use single-dose vials of drugs that are discarded after each administration (207,364). In-line bacterial and particulate filters and simplified catheter flushing procedures are additional infection control measures (see below).

Drug Administration

The supplies used in drug administration depend on the delivery system being used.[9] Most patients have separate tubing-the ***administration set—that***

[8] **Although peripheral and midline catheters are treated in this chapter as equipment, they are usually considered supplies because they are not reusable.**

9 Patients who use elastomeric bladder **devices may not need additional administration tubing because the bladder pump comes with tubing.**

connects the infusion device to the catheter. Administration sets, which come in varying lengths and configurations, must be changed on a regular basis to prevent infection, clogging, and harmful drug decomposition or interaction (174). Some administration sets have special extensions for 'piggyback' infusions, where a second drug is administered through a Y-gap at the patient's end of the administration set, thereby avoiding mixture of the two drugs in the tubing. Many electronic infusion devices require administration sets that are designed specifically for that pump (103). Extension tubing is also available to increase the patient's mobility during drug administration.

The INS recommends that administration sets be changed at least every 48 hours (174). However, some types of drugs and drug regimens require that tubing be changed with every new drug administration (15).[10]

Injection ports are rubber caps that are attached to the administration set or directly to the catheter and are used for the periodic injection of drugs or other solutions into the vascular system (174). Ports that are integral to the administration set are changed whenever the administration set is replaced. Ports attached to peripheral catheters should be replaced whenever the catheter is changed, and ports on central catheters should be changed at least every 7 days (174).

In-line filters may be attached to administration sets to prevent air, particulate matter, or bacteria from entering the vascular system and causing infection or other complications. The cost-effectiveness of using in-line filters has been the subject of some debate (5,107,117,147,277), and practices vary among HDIT providers (3,15). INS standards, however, advocate their use inmost cases (174).

The type of filter needed varies depending on the therapy. A small (0.2 micron) filter is recommended for routine use in most IV therapy because it prevents bacteria as well as air and particulate matter from entering the vein (174). Transfusion of blood and blood products requires special falters, with a separate filter used for each unit of blood product transfused so that signs of contamination can be traced to a specific unit. Special surfactant-free filters are required for intraspinal infusion of any medication (174).

Some in-line falters are add-ens that must be attached to the IV administration set; others are integral to the infusion device or the IV administration set itself. The INS recommends that *in-line* falters be changed each time the administation set is changed (every 48 hours) (174). A recent study, however, found that some disposable in-line antimicrobial filters lose their ability to retain bacteria after 24 hours (27), indicating that more frequent change might be appropriate.

Catheter and Site Care

Patients with either central or peripheral vascular access must care for their catheters and the site where their catheter exits the body in order to minimize risk of catheter malfunction (e.g., clogging or breakage), site irritation, and secondary infection. The following are typical methods used to accomplish this care.

- *Catheter protection—To* protect a catheter from contamination between doses, special cannula caps are used. The INS recommends that these caps be replaced whenever they are removed to minimize risk of infection (174).
- *Catheter site care—The INS* recommends that the bandages (dressings) that cover the exit site of a catheter be changed at least every 48 hours or whenever they are soiled, wet, or loose (174). Dressing changes can be conveniently performed by the patient or caregiver at the same time as administration set changes. When dressing change coincides with rotation of a peripheral IV site, it may be performed by the skilled nurse. For subcutaneous ports, dressings need only remain in place when the port is accessed by a needle.
- *Catheter flushing-AIl* catheters are susceptible to clogging either by the patient's own blood or by other deposits (174,396). For this reason, most catheters are flushed periodically, most commonly with saline (salt solution) or with heparin, an anticoagulant.[11] Catheters are

[10] For example, when two incompatible drugs are infused through the same catheter, the administration Set mUSt be changed between drugs (174). Also, some drugs with limited periods of stability may form precipitates after a certain number of hours (15). When these drugs are being infused, IV administration tubing must be changed with every new drug admiffitration (15).

[11] Heparin is used because it is the only soluble anticoagulant.

Box 3-B-Controversy Over Catheter Flushing Methods

The issue of saline v. heparin v. SASH (saline-administration-saline-heparin) flushing is one of considerable debate, and literature exists to support the relative efficacy and cost-effectiveness of each method (18,72,104,124,144, 166,245,337). There is as yet no consensus on which method is most appropriate, and practices vary among providers (36). Current published standards suggest that the SASH method should be the exception rather than the rule (174). However, some home infusion providers use the SASH method with every type of therapy because they believe it results in decreased complications (36,402).

One argument against the use of the SASH procedure (as opposed to heparin or saline alone) as a default for catheter flushing is that it increases the risk of infection because it necessitates multiple accesses to the catheter lock (36). Risk of conlamination may also be increased when catheter flushing substances are provided to the patient in multiple-use vials. Although some home infusion therapy providers supply patients with a larger vial of heparin solution from which they fill their own syringe for each flushing procedure (181), most providers use prefilled syringes to avoid increased risk of contamination and to simplify the procedure for the patient (181,402). One medical equipment company has recently introduced a closed, 3-chamber SASH flushing system that reduces to one the number of catheter accesses required (40). Some catheters are pre-heparinized or have special valves at each end that minimize the backflow of blood into the catheter, decreasing the need for flushing (138,260).[1]

[1]Pre-heparinized catheters can only be used inpatients who are not sensitive to heparin and with heparin-compatible drugs. These catheters may be routinely flushed with saline alone (260).

generally flushed after each administration of medication and after the drawing of a blood sample. When two incompatible drugs are administered through the same catheter, or when the drug being administered is incompatible with heparin, a special flushing procedure called the SASH (saline-administration-saline-heparin) method is often used. In this procedure, the catheter is flushed with saline before and after administration of the drug to avoid any contact with the heparin solution (174). Catheter flushing supplies are often delivered to the patient in prepackaged kits. There is considerable variation among providers in the flushing methods they recommend to patients (see box 3-B).

. *Catheter clearance—The* risk and expense of surgically replacing a clogged central catheter can sometimes be avoided by using urokinase, an enzyme that helps degrade clots and restore catheter patency (2). The urokinase is injected into the catheter using a syringe and allowed to sit for several minutes before the catheter is aspirated to remove the clot (2). This procedure must be performed by a skilled nurse or a physician (260).

Table 3-2 describes variation in the frequency of procedures required by HDIT patients with different types of vascular access devices and therapeutic regimens.

Certain therapies require special techniques and supplies. For example, home transfusion patients may need special warmers to bring blood products to normal body temperature prior to infusion (174). Patients on antineoplastic therapies need special supplies to protect them from exposure to these toxic drugs when performing routine catheter maintenance or drug administration (174). Patients on intraspinal therapy need special diluent solutions and in-line filters because many preservatives, stabilizing agents, antioxidants, and surfactants[12] typically found in dilutents and filters can cause nerve damage if they enter the intraspinal area (100,202).

Services and Staffing

HDIT involves a broad range of services, including patient screening and assessment; patient training; and ongoing medical, pharmacy, nursing, laboratory, delivery, and coordination services. These services, in turn, are performed by a variety of health professionals, including registered nurses (RNs), RN specialists (e.g., IV, oncology, and critical care

12 A surfactant is a substance added to a solution to reduce surface tension of the fluid. The use of surfactant-containing antimicrobial or particulate filters on intraspinal administration sets is strictly contraindicated because surfactants often contain alcohol (202).

Table 3-2—Recommended Routine Frequency of Selected Catheter Maintenance Procedures Performed for Home Infusion Therapy Patients, by Type of Vascular Access Device[a]

Vascular access device	Procedure				
	Catheter Change[b]	Needle Change[c]	Catheter flushing[d]	Dressing change[e]	Administration set Change[f]
Peripheral catheter					
Venous	● 48 hours	NA	Variable	48 hours	48 hours
Arterial	● 96 hours	NA	Variable	48 hours	48 hours
Midline catheter	● 48 hours	NA	Variable	48 hours	48 hours
Central venous catheter					
Tunneled catheter	NA	NA	Variable	48 hours	48 hours
Nontunneled catheter	NA	NA	Variable	48 hours	48 hours
Peripherally inserted central venous catheter	NA	NA	Variable	48 hours	48 hours
Totally implanted catheter	NA	7 days	Variable	NA	NA
Subcutaneous Infusion	NA	● 48 hours	NA	48 hours	48 hours

NOTE: NA = not applicable. Asterisks (*) indicate that this procedure can only be performed by a qualified health professional-usualiy a registered nurse. Some procedures may be performed by a nonskilled person (e.g., patient or caregiver). In many cases, the functional ability of the patient determines who will perform thetask. In some cases, the patient's medical condition may be such that skilled personnel are requiredtoperform what would normally be nonskilled functions (e.g., a dressing change if the catheter site shows signs of infection). Nonskilled procedures may also be performed by skilled staff in conjunction with skilled procedures (e.g., a dressing change when a peripheral catheter site is rotated).

[a]Frequencies reflect recommendations of the Intravenous Nurses Society in its revised standards of practice for intravenous nursing (both in inpatient and outpatient settings). Actual frequency of procedures may vary among providers.

[b]Catheters other than peripheral or midline are not routinely changed, but change maybe necessary if an infection or malfunction occurs.

[c]The needles on implanted catheters can remain in place for up to 7 days, and all infusions and heparin flushing can be achieved through that needle.

[d]Catheters are generally flushed after each administration of medication andafterabloodsample isdrawn; hence, flushing could occur as infrequently as once a week for patients on continuous infusion or as often as four times a day for patients on four times a day antibiotics. Frequency and type of flushing depends on type of catheter and drug being used. When not in use, catheters require less frequent flushing.

[e]Dressings must also be changed whenever they become soiled, Wet, or loose.

[f]For patients on continuous infusion of chemotherapy via an Infusion pump with a multiple-day drug reservoir, set can be left in place until reservoir is changed.

SOURCES: Intravenous Nurses Society, Intravenous Nursing Standards of Practice (revised1990), *Journal of Intravenous Nursing* Supplement 1990, April 1990; OTA site visits to providers, 1990-91.

nurses), licensed practical nurses, nurses' aides, pharmacists,pharma cy technicians, and other on-the-job trained personnel. Because HDIT is a relatively new mode of practice, providers generally look for employees with extensive hospital infusion therapy or pharmacy experience and rely heavily on in-house training to prepare their staff for the specific demands of HDIT patients (364). For some nurses and pharmacists, HDIT practice is an attractive career choice because it allows them to gain independence and further their career in ways that practice in other settings does not (364).

The distribution and coordination of responsibilities among HDIT staff depend on the organizational structure of the home infusion provider, the capabilities of individual staff, limitations of State licensure and practice acts, and size of the geographic service area. For example, pharmacy-based providers often utilize clinical pharmacists for patient assessment, education, and clinical monitoring tasks (see box 3-C), while nursing-based providers place these responsibilities in the hands of nurses.[13] Small providers with limited staff and a small service area may have one pharmacist and one nurse as the sole providers of services. Other providers may contract with home health agencies or visiting nurses associations to provider nursing services to patients in more remote areas (see ch. 4). Large, full-service providers in concentrated metropolitan areas may organize their many nursing personnel into teams responsible for the care of a defined group of patients and rely heavily on central coordination staff to ensure that services are delivered properly and in a timely fashion (box 3-C).

The next section describes in more detail the specific services involved in HDIT and the qualifications, abilities, and availability of the staff who provide those services.

[13] See ch. 4 for a description of the different types of HDIT providers.

Box 3-C-Staffing and Organization of Home Drug Infusion Therapy Services: Two Contrasting Models

Anne Arundel General Hospital Outpatient IV Therapy Services Program, Annapolis, MD

Outpatient specialists are pharmacy technicians with a minimum of 3 years' hospital experience. Under the supervision of pharmacist staff, they are responsible for patient training, care coordination, and preparation of all IV medication in the outpatient center pharmacy facility.

The RN specialist, a registered nurse (RN) with extensive experience in hospital IV therapy, is responsible for the initial patient assessment, some patient training, and all peripheral catheter insertions and changes. The RN specialist also plays an active role in training outpatient specialists and any other health professionals who may become involved in home IV therapy services (e.g., home health nurses who see homebound patients).

Clinical pharmacists are Pharm.D.s with hospital pharmacy experience and a minimum of 2 years' experience in a clinical setting. They are responsible for designing and monitoring therapy and examining patients in the outpatient center three times per week, Although the pharmacists do not diagnose and treat patients, they do examine patients and report any concerns immediately to the physician for further investigation. Pharmacists are also directly involved in developing and prescribing therapy regimens, under the supervision of staff physicians.

The microbiologist performs and/or coordinates IV therapy-related laboratory work which is generally done at the referring hospital.

Physicians see patients at least once a week in their offices or in the outpatient center and consult with the pharmacist and other staff about patient progress, therapeutic changes and response, etc. A medical director is on staff at the center.

ABEL Health Management Services, Inc., Great Neck, NY

Field nurses are primarily RNs with strong clinical skills and experience, although some are licensed practical nurses (LPNs). Field nurses are organized in teams depending on their qualifications and availability. Each patient is assigned a team of field nurses who share call duty. Each field nurse is equipped with a 4-wheel-drive vehicle, car phone, fax machine, and 24-hour beeper. Field nurses average 6 to 8 patients per day overall, but the number for any one nurse depends on geography and patient needs.

Patient education specialists are baccalaureate-prepared RNs who do initial patient assessments and initiate the patient training process (field nurses finish it). They also train other staff in home infusion techniques.

Nursing care coordinators (NCCs) are baccalaureate-prepared RNs who serve as the point persons for all communication from nursing, pharmacy, lab, and patients. They generally do not perform clinical functions.

Nurse managers are baccalaureate-prepared RNs who are responsible for overseeing the activities of NCCs and managing and monitoring any problems that may arise.

Clinical pharmacists are registered pharmacists (R.Ph.s). They are responsible for coordination of all clinical functions of pharmacy service, including receiving physicians' telephone prescriptions, maintaining patient medication profiles and checking for possible drug interactions, providing drug information to other nursing and pharmacy staff, and reviewing patient lab work. They are recruited from both retail and hospita1 settings and undergo 8 to 10 weeks of initial training in infusion therapy techniques before assuming full staff responsibility.

Staff pharmacists are R.Ph.s who are primarily responsible for drug preparation and compounding.

Pharmacy liaisons are on-the-job trained personnel who act as support staff for staff and clinical pharmacists, aiding in the preparation of drugs and facilitating communication between nurses, physicians, pharmacists, and patients.

Other staff include customer service representatives (responsible for distribution of drugs, supplies, and equipment), armed escorts for staff who serve patients in dangerous neighborhoods, and others.

SOURCES: Anne Arundel General Hospital Outpatient IV Therapy Services Program, Annapolis, MD, informational visit with OTA staff, Oct. 25, 1990; ABEL Health Management Services, Inc., Great Neck, NY, informational visit with OTA staff, Nov. 9, 1990.

Patient Screening and Assessment

Patient screening is perhaps the most critical element in the decision of whether or not to administer HDIT (see ch. 2), and it is the first service an HDIT provider renders to a prospective patient. In determining candidacy for HDIT, the provider must consider the patient's medical condition, the patient's and caregiver's willingness and ability to perform self-care, and the environmental characteristics of the home setting. These considerations must be balanced against both the demands and associated risks of the prescribed HDIT regimen and the level of services the provider itself is capable of delivering. At a minimum, patient assessment includes a visit to the patient in the hospital prior to discharge, in which the patient's medical stability is evaluated and where the patient is questioned about other relevant aspects of the home and family environment. In addition, it may include a visit to the patient's home to confirm that the home environment is suitable (24). Patients who are referred from outpatient care may receive their assessment visits in a physician's or provider's office.

Although the actual assessment is usually performed by a nurse (364), other professionals (e.g., physician, social worker, clinical pharmacist, dietitian) may also participate (24,270,335). Box 3-D provides an example of criteria that one home IV antibiotic therapy program uses to screen patients.

Patient Characteristics

The overall condition—medical, physical, mental -of a patient will affect the level and nature of care required. Specific conditions that typically affect administration of IV therapy in the elderly include cardiovascular disease, poor venous access, thinning of the skin and underlying tissues, diabetes, joint disease, paralysis, effects of long-term use of certain drugs, and poor response to acute disease processes (62). Therapeutic decisions and patient safety may also be complicated when a patient is taking other drugs in addition to the prescribed therapy. HDIT can only be safe and effective if the nurse and pharmacist are aware of the patient's individual needs and (in conjunction with daily caregivers) can anticipate and handle related complications.

Some elderly patients are fully capable of performing self-care and need only periodic skilled nursing services to receive HDIT. Other patients who normally require no assistance may have specific fictional or cognitive problems that limit their ability to perform the specific self-care procedures associated with HDIT. These patients require more supportive services to make HDIT feasible and safe.

Still other patients require assistance with normal activities of daily living even *without* infusion therapy due to certain conditions that are especially prevalent among this population. For example:

- Eighty-six percent of elderly persons have one or more chronic conditions, compared with 50 percent of the general population (361).

Box 3-D—Patient Screening Criteria for One Home Intravenous IV) Antibiotic Therapy Program

Disease Criteria
- . Infection responded clinically/clinically stable
- . Has not had a fever for at least 5 days prior to discharge
- Only in hospital for IV therapy

Treatment Criteria
- . Good venous access
- Received and tolerated IV antibiotics in hospital

Patient Criteria
- Alert
- Cooperative
- . Average intelligence
- Good motivation
- . Reliable
- . Emotionally stable
- Acceptable lifestyle/home environment
- . Likelihood of compliance
- No history of mental problems or substance abuse
- . Understands therapy and gives consent
- . Patient and one family member taught
- . patient's family agrees to therapy
- Adequate support system at home
- Completed IV training session
- Proficiency in IV techniques
- Can care for venous catheter and reliably self-administer antibiotics
- Telephone and refrigerator at home
- . Access to health area
- Transportation available

SOURCE: K. Lee and J.I). Andrews, "Assessment of the Need for a Home Intravenous Antibiotic Program," *Canadian Journal of Hospital Pharmacy* 41(6):295-301, *307,* December 1988.

- Dementia, which can limit both cognitive and functional capacity, affects an estimated 15 percent of persons of 65 years of age or over, compared with approximately 1 percent of younger persons (336,339).[14]
- Depression, which can also cause cognitive and functional impairment, affects 2 to 10 percent of the elderly (39,139).
- Visual and auditory impairment, which can limit a patient's ability to learn and perform self-care functions, are common among the elderly. Nine percent of persons 65 years of age or older are visually impaired, and 32 percent of elderly persons are hearing impaired (4).
- Orthopedic impairments or deformities, which can limit a patient's ability to perform self-care, are present in 13 percent of the elderly compared with 8 percent of the general population (361).
- Within the population with chronic conditions, the rate of functional limitations is much higher for the elderly: 18 percent of elderly people with chronic conditions reported limitation in a major normal activity of daily living,[15] compared with 4 percent of the general population with such conditions (361).
- Two-fifths of community-dwelling elderly 65 years of age and over report limitation in a major normal activity of daily living, compared with 14 percent of the total noninstitutionalized population (361).

The patient's role in HDIT will vary depending on the type of therapy, venous access device, and drug delivery device. Some drug delivery systems and access devices require considerable manual dexterity and physical mobility to operate. For example, a patient on a gravity drip system must be able to reach the bag, remove it from the IV pole or hanger, change the bag, and assemble anew set of tubing. A bedridden patient with debilitating arthritis would be incapable of performing these tasks. In the absence of a capable caregiver, the patient could be put on an automatic drug delivery system (e.g., a fully programmable infusion pump) that would greatly reduce the amount of effort required on the part of the patient. Some patients, however, would be too debilitated to operate even the simplest infusion pump and would require assistance in drug administration either by an informal caregiver or a nurse.

A patient who is willing and physically able to administer HDIT may still be unable to do so due to cognitive barriers. For example, an impaired patient who is instructed in central catheter care and administration of his or her specific drug regimen may be able to repeat the required procedures perfectly right after training but may be unable to repeat them on the following day.

If a patient is incapable of performing the required self-care, a capable and reliable home caregiver must be available for HDIT to be feasible. Even when the patient is capable of self-care, an additional trained caregiver can be an important backup mechanism should the patient become temporarily or permanently unable to perform certain tasks (24,209,335). For patients who require 24-hour attention (e.g., some terminal cancer patients), more than one home caregiver maybe required for the safe administration of therapy (246). Dysfunctional patients with no available caregiver may be able to receive HDIT if the risks of that therapy are not life-threatening, but these patients will require considerably more paid nursing visits (table 3-3).

Regardless of their clinical stability and objective ability to perform the required tasks, some patients may simply be unwilling to undergo treatment in the home setting due to fear or discomfort with the therapy, equipment, or associated risks. Unwillingness is an absolute contraindication to HDIT; providers and the published literature unanimously agree that safe *and effective home therapy cannot be provided to patients (or by caregivers) who do not want to be on it. The* right of the patient (or the caregiver) to decline treatment in the home setting in spite of the urging of other interested parties is an issue of quality assurance as well as of patient rights.

Home Environment

In order to safely and effectively carry out HDIT, a home must have certain basic features. These include running water, electricity, refrigerator space for drug and supplies storage, a clean area where aseptic catheter and simple wound care can be performed, and, perhaps most importantly, access to a telephone for emergency and routine communica-

14 Includes moderate and severe dementia.

15 For example, housekeeping.

Table 3-3-Average Number of Nursing Visits Per Week for Home Infusion Therapy Patients, by Selected Types of Vascular Access Device, Type of Therapy, and Functional Status of Patient[a]

Type of vascular access device and therapy	Number of skilled nursing visits per week[b]	Number of other nursing or assistive service visits per week if patient/caregiver.[c]	
		can perform all drug administration and self-care tasks	cannot perform any drug administration or self-care tasks
Peripheral or midline venous catheter			
Hydration therapy once a day...	2 to 3	0	7
Antibiotics three times a day.	2 to 3	0	21
Tunneled or nontunneled central catheter or peripherally Inserted central catheter			
Hydration therapy once a day...	1	0	7
Antibiotics three times a day	1	0	21
Continuous chemotherapy or pain management with infusion pump.	1 to 2[d]	o	2 to 3
Totally Implanted catheter			
Hydration therapy once a day.	1	0	7
Antibiotics three times a day	1	0	21
Continuous chemotherapy or pain management with infusion pump.	1 to 2[d]	o	2 to 3
Totally implanted pump	1	0	0
Continuous subcutaneous morphine Infusion with Infusion pump	3 to 4	0	0

[a]Represents the average minimum number of recommended nursing visits per week for drug administration, catheter care, and dressing change based on recognized standards of infusion therapy practice and actual practice of current home infusion therapy providers. Nursing visits maybe more frequent toward beginning of therapy as patient is still becoming familiar with self-care techniques. Number of visits will vary depending on medical condition of patient and occurrence of infusion therapy-related complications.

[b]Does not include initial assessment and training visits. Does not include additional skilled nursing visits (up to three per week) required for drawing blood samples for laboratory monitoring. The minimum of one skilled nursing visit for ail types of patients and therapies is for ongoing skilled assessment and monitoring of patient's condition.

[c]Does not include separate supplies delivery visits. Does not reflect reduction i, nonskilled visits due to performance of nonskilled tasks during skilled nursing visits.

[d]D_{epen}ds on capacity of pump's drug reservoir.

SOURCE: Office of Technology Assessment, 1992. Based on information from: *Intravenous Nurses Society, Intravenous Nursing Standards of Practice* (revised 1990), *Journal of Intravenous Nursing* Supplement 1990, April 1990; A.L. Plumer and F. Cosentino (eds.), *Principles and Practice of Intravenous Therapy 4th Edition (New York, NY:* Little, Brown and Company, 1987); Perivascular Nurse Consultants, Rockledge, PA, information on frequency and cost of infusion therapy nursing visits, provided to OTA Jan. 18, 1991; L.C. Hadaway, "An Overview of Vascular Access Devices Inserted via the Antecubital Area," *Journal of Intravenous Nursing* 13(5):297-306, September/October 1990; information provided to OTAby home drug infusion therapy providers, manufacturers, and others, 1990-91.

tion between the patient and home infusion therapy staff (24,364). In certain instances, some of these features may not be necessary (e.g., some drugs need no refrigeration). Generally, however, the HDIT provider must ascertain during initial patient assessment whether the patient's home is adequately equipped for the patient's particular therapy needs (24).

Other characteristics of the home environment can also pose problems for HDIT For example, large pets or small children may tamper with the drug delivery system (tubing, buttons on a computerized infusion device), potentially interrupting a dose or causing more serious harm to the patient.

Proximity to Service Provider

Accessibility of needed services, drugs, equipment, and supplies is another important consideration in the patient screening process. In an urban area, patients may be close enough to an HDIT provider to obtain emergency drugs, supplies, equipment, or services within a short time. Patients in areas more remote from the provider, however, may have to wait longer to obtain the supplies or services they need.

This problem can be addressed in part by the decentralized provider model. For example, an infusion company in an urban location may contract with a local home health agency to provide skilled nursing care to a patient in an outlying area. Because there is no guarantee that the local home health agency nurses possess the knowledge and skills required for HDIT maintenance, the infusion company may have to provide special training to these nurses before releasing a patient to their care. For patients who are either very ill and require intensive services or who are in an area where skilled home

Box 3-E—Screening Critetia for Home Transfusion Therapy Patients

In order to be accepted for home transfusion therapy, the American Association of Blood Banks (AABB) recommends that patients meet all of the following criteria:

. They are not ambulatory (mobile patients are more appropriately treated in hospital or outpatient facilities);
They have a stable cardiorespiratory status (i.e., no recent history of acute angina or congestive heartfailure);
The patient's transfusion history has been carefully screened, paying special attention to reactions (if present) and appropriate chronic diagnoses;
They did not experience a reaction during the administration of their last transfusion;
• They are cooperative and able to respond to verbal commands;
• **They we able to detect and respond** appropriately to body symptoms;
. A responsible adult is present during the duration of the transfusion (this does not include the nurse), presumably to assist in getting emergency services to the patient in the event of a situation that requires the nurse to give the patient undivided attention;
• A working telephone is available during the transfusion; and
• The patient's medical condition is suitable for home transfusion. (Diagnoses the AABB considers potentially appropriate for home transfusion therapy include chronic gastrointestinal bleeding, anemia in the presence of chronic renal disease, anemia with bone marrow failure, anemia associated with malignancies, sickle cell anemia, and thalassemia).

SOURCE: American Association of Blood Banks, *Improving Transfusion Practice: The Role of Quality Assurance,* **S. Kurtz, S. Summers, and M. Kruskall (eds.) (Arlington, VA: American Association of Blood Banks, 1989).**

nursing services are simply not available, HDIT may not be a reasonable alternative.

Disease- and Therapy-Specific Considerations

Some patients-either due to complications stemming from their medical condition or other factors (environmental and social) that can interfere with the safe and successful administration of infusion therapy-will require special consideration and attention by HDIT providers. Acquired immunodeficiency syndrome (AIDS) patients, for example, are highly susceptible to infections, which may affect decisions regarding their treatment (e.g., which kind of catheter to use) (238).[16] AIDS patients on HDIT who have a history of IV drug abuse will require close monitoring to assure that they are not using their venous access devices for self-administration of illicit drugs. Also, patients with AIDS-related dementia may be unable to understand or perform self-care functions adequately (238). Although the patient may be able to perform self-care initially, he or she is likely to lose that ability as the dementia progresses. Ongoing nursing assessment is key in determiningg the specific home infusion therapy needs of AIDS patients.

Home blood transfusion patients also require special consideration. The American Association of Blood Banks (AABB) has published specific criteria that patients should meet before they can receive in-home transfusion (see box 3-E).

Ongoing HDIT Services

All HDIT involves at some level medical, pharmacy, nursing, laboratory, and coordination services. Although the exact responsibilities of each of the types of service personnel (e.g., nurses or pharmacists) varies among infusion providers (see box 3-C), all of the basic services must be available for HDIT to take place. The setting in which specific services are delivered varies depending on both the provider and the patient (see ch. 4). Some patients receive all services in their home; others receive some services in an outpatient center but administer the drugs themselves at home; still others receive their infusions in a physician's office or outpatient center and have no home care or self-care responsibilities at all. The following describes existing variation in how certain HDIT services are provided and by whom. It does *not* attempt to define optimum arrangements.

16 Studies suggest **that tunneled central catheters present a lower risk of site infection than surgically implanted ports or percutaneously inserted catheters (238).**

Medical Services

All professional services provided to HDIT patients must be overseen by the patient's physician, who prescribes the therapy and orders the home care. The physician has primary responsibility for informing the patient about the anticipated results and potential complications of therapy, and the physician is consulted in the case of emergency or lesser complications of therapy. The physician also receives the results of laboratory tests and orders any necessary changes in the therapy, based on the results of those tests and on the patient's visits to the physician during the course of the therapy.

The extent of physician involvement during the course of HDIT can range from an arm's-length role (e.g., endorsing prescription changes suggested by the home infusion pharmacist) to a highly interactive one (e.g., seeing patients several times a week and initiating any therapy changes). Physician involvement is affected by both clinical and nonclinical considerations. Some medical conditions routinely demand frequent physician contact (either over the telephone or an actual patient encounter), while others can be followed by a skilled nurse who reports patient progress and complications back to the referring physician. Patients in poor physical health may need to see a physician more frequently than otherwise healthy patients on HDIT. Some programs recommend weekly physician visits for patients on antibiotic therapy, to confirm patient response to therapy and monitor progress in the resolution of infection, but this practice is apparently not universal *(96,364).*

organizational characteristics of an HDIT provider can also influence the frequency of physician-patient or physician-staff contacts. A center-based provider, for example, has patients come to an outpatient center for their supplies, catheter site changes, physician visits, and other professional services (15). Other HDIT providers play a less active role in ensuring patient-physician contact; many leave the scheduling and frequency of followup visits entirely to the discretion of the referring physician (203,364).

Patient Training

Patient education is required before a particular patient begins home therapy. At a minimum, this service includes a visit to the patient in the hospital prior to discharge, where the patient's ability to perform the needed infusion-related functions are affirmed (24). In addition, patient education maybe continued once the patient has returned home. Patients are instructed in infusion techniques, site care, the nature and risks of their therapy, drug storage and stability, equipment maintenance and use, recognition of signs and symptoms of possible complications, and recordkeeping (134,209). This instruction may be performed by one or more of a number of professionals, including nurses, pharmacists, and medical equipment personnel proficient in the use of a particular infusion pump. Written instructional materials should be provided for reference and reinforcement of skills (209,364).

The time required for instruction varies depending on the level of complication involved in that care and patient factors (209,364). Sometimes the initial training visit must be followed up with one or more additional visits to ensure that the patient is indeed capable of and comfortable performing the necessary procedures (240,364). All instruction should be documented in the patient record (209). Many providers have patients sign forms stating that they have been instructed in and are capable of performing the requisite self-care (209,364).

Pharmacy Services

At the least, HDIT pharmacy services involve compounding the drugs to be infused, educating nurses and patients regarding potential drug interactions and side effects, monitoring the patient's drug regimen, and being available to respond to concerns regarding the therapy. Pharmacist responsibilities may also extend to participating in patient education regarding self-care technique; monitoring patients via conversations with nurses or patients themselves; monitoring laboratory results; collaborating with physicians in establishing drug regimens and making prescription changes; and, in some cases, educating physicians about which therapies are safest and most effective in the home setting (14,24). Home infusion pharmacists also monitor patients during therapy and consult with the referring physician on patient progress (24,364). The degree to which a pharmacist talks on the telephone or visits the patient in his or her home varies depending on the provider.

An infusion pharmacy differs dramatically from most retail pharmacies. While retail pharmacies generally dispense only oral medication, infusion pharmacies must have the equipment necessary to

safely prepare and store parenteral solutions. These usually include laminar flow hoods to reduce risk of contamination,[17] modified storage areas for certain drugs, and additional supplies and equipment needed for mixing solutions (364).

How a parenteral drug is prepared depends on: 1) the specific drug prescribed, 2) the dosage, and 3) the type of drug delivery system (149). Preparation can include mixing or titrating to the proper concentration. Some therapies, such as hydration therapy, require little preparation because the solutions come in premixed bags with varying dilutions of dextrose. Other therapies require more extensive preparation either in-pharmacy (e.g., an antineoplastic drug must be prepared in a special vertical flow cabinet) or in the patient's home.

Some infusion delivery systems require specialized in-pharmacy computer hardware. One type of infusion pump sometimes used for multiple drugs, for example, has a removable microchip that must be programmed in the pharmacy. Another newly developed pump requires a barcode labeler in the pharmacy (40).

Some pharmacy-based providers delegate drug compounding tasks to pharmacy technicians who are supervised by managerial pharmacists (149). Others use only registered pharmacists for drug compounding (see below) (3).

Pharmacist Training and Recruitment—Although some formal training in infusion pharmacy is available, it is not a nationally recognized specialty .18 The pharmacy profession includes baccalaureate-prepared registered pharmacists (R. Ph.s), who undergo a 5-year training program, and doctoral-level pharmacists (Pharm.D.s), who complete 6 years of training (385).[19] Either one of these degrees is required for Iicensure in all States (385). Residency training in hospital pharmacy, clinical pharmacy, and a variety of other specialties is also available (385). A 1989 survey of the 74 schools of pharmacy in the United States[20] found that 42 offered some form of instruction specific to home infusion therapy (224). Of those 42, only 13 had a course primarily devoted to home infusion therapy, and only 2 schools required all their students to take that course.

Home infusion pharmacists are quite different from retail ("community drug store' pharmacists, who usually have comparatively little experience in infusate compounding techniques or the pharmacokinetic[21] aspects of infusion therapy (14). Existing standards for home infusion therapy providers make explicit a wide range of proficiencies that a community pharmacist must have in order to be an accredited infusion therapy provider (see ch. 5) (179,237). Although most States do not have a separate license category for infusion pharmacists, an increasing number of States license and regulate pharmacies that prepare drugs for infusion (210). These laws act as a "back door" regulatory mechanism for the practice of home infusion pharmacy by mandating certain physical plant characteristics and staff proficiencies.

Thus, although some pharmacists may receive formal training in home infusion therapy techniques, the majority of training takes place on the job. Many HDIT providers rely on hospitals as both recruitment and training grounds for their pharmacists, requiring anywhere from 1 to 3 years previous hospital pharmacy experience (364). Additional training, both initial and ongoing, is provided to these pharmacists on the job (364).

Physician acceptance of the pharmacist in an expanded clinical role varies. Some physicians value pharmacists' contributions greatly and rely upon them extensively for advice in drug therapy decisions, while others consider pharmacists' involvement an encroachment on physician's clinical decisionmaking (177,329). Physicians coming out of training today are more likely than their predecessors to have had interdisciplinary training experiences and hence may be more aware of and

17 Some infusion pharmacies have specially constructed, positive pressure "clean rooms" for the preparation of parenteral solutions. While these do provide an additional level of protection against contamination, they are costly to build and are not required in existing infusion pharmacy standards (178331,237).

18 There are currently three nationally recognized pharmacy specialties: nuclear pharmacy, pharmacotherapy, and nutritional p harmacy. The American Society of Hospital Pharmacists is proposing two new specialties, psychopharmacy and oncology pharmacy (14).

19 Both programs include baccalaureate education.

20 All 74 schools responded to the survey.

21 Of or pertaining to characteristic interactions of a drug and the body in terms of its absorption, distribution, metabolism, and excretion (393).

accepting of the capabilities of the clinical pharmacist (177).

Pharmacy Technician Training and Recruitment—Larger infusion providers often employ pharmacy technicians to assist pharmacists in compounding drugs. Pharmacy technicians are trained either on the job or in 2-year certificate programs (14,385). The American Society of Hospital Pharmacists (ASHP) accredits technician training programs in hospitals and community and vocational colleges (14). In 1988 there were 68 formal training programs in 19 States, of which 11 were accredited by ASHP (385).

The degree to which HDIT providers use pharmacy technicians to compound drugs depends on State practice acts and licensure mechanisms. Four States (Illinois, Massachusetts, Michigan, and New Hampshire) offer certification exams for pharmacy technicians, and three States (Illinois, Nevada, and Washington) require licensing (385). In some States (e.g., California and Arizona), pharmacy technicians in retail pharmacies cannot compound or otherwise prepare drugs (186). This may explain the fact that, although pharmacy technicians can be found in hospitals in all States, 9 States have no pharmacy technicians in retail pharmacies (385).

Nursing Services

HDIT services that must be provided by a skilled nurse (usually an RN) include:

- patient education regarding administration of the infusion and care of the infusion site,[22]
- periodic monitoring of the catheter exit site for signs of infection or other complications,
- peripheral catheter site changes,
- peripherally inserted central catheter placement,
- drawing blood samples for laboratory tests, and
- general monitoring of the patient's health status.

Many other tasks (e.g., dressing changes, drug administration, general catheter maintenance) can be performed by less highly skilled personnel under the direct or indirect supervision of IV nurse specialists. These personnel (including licensed practical nurses, nurse aides, and home health aides) can play an especially important role for patients with limited self-care ability. They may also be involved in ongoing service coordination activities, acting as liaisons between patients and staff.

The amount and skill level of nursing services required by an HDIT patient varies dramatically depending on the route of administration, type of drug delivery system, type of therapy, and functional status of the patient (see table 3-3). For example, a patient with a peripheral catheter who receives antibiotics 4 times a day will need a skilled nursing visit every 2 to 3 days for catheter site changes. At the other extreme, a patient with a totally implanted catheter may need only weekly visits. Skilled nursing visits for these latter patients generally consist of catheter site inspection and other monitoring activities. Patients unable to perform self-care procedures may need additional paid assistive services on a daily basis if no family caregiver is available.

Additional skilled visits may be needed for patients who require frequent laboratory tests (see ch. 2). Drawing blood, either directly from a vein or through a catheter, is a skilled procedure that must be performed by or under the direction of a skilled nurse or phlebotomist.

Placement of peripheral catheters (including midline catheters) must be performed by an RN with training and experience in this procedure (174,291). The procedure usually takes from 10 to 20 minutes to perform, although it may take longer if the patient has poor venous access or other complicating conditions (291). Peripheral lines and midlines are usually inserted in the patient's home (291,364).

Insertion of a PICC line is a more involved and highly skilled procedure that takes from 1 to 2 hours to perform (see box 3-F) (291). In order to place a PICC line, an RN must have special training and experience (174,291). INS standards require radiographic confirmation of PICC line placement (174), which is most convenient to perform in a hospital or outpatient setting where x-ray facilities are available. However, some nurses reportedly perform PICC line insertions in the patient's home either with or without portable x-ray equipment (291). The ability of RNs to perform PICC line insertion is limited by availability of training and by State nurse practice acts (see box 3-F). Although this particular area of specialty practice has yet to be officially recognized and is even prohibited in some States,

[22] Pharmacists may also participate in patient education activities.

Box 3-.F—The Peripherally Inserted Central Catheter (PICC Line): New Technology and Nursing Practice

The PICC line is an example of how recent technological advances innfusion therapy are shaping new areas of nursing specialty practice. Insertion of a PICC line is a highly skilled procedure that can be performed only by a physician or by registered nurse with special training (174,291). The procedure involves:

* measuring the patient to determine the length of catheter required;
* aseptic/ antiseptic preparation of the catheter entry site;
. insertion and threading of the catheter
. radiographic confirmation of catheter placement; and
. suturing and dressing of the exit site (50,291).

Although training in PICC line insertion technique is widely available, the quality of training programs varies tremendously (291). Some courses are 8 hours long and involve no practice on live subjects. other courses are longer and require numerous supervised and documented successes on live subjects. Some programs present "certificates" to participants on completing the course, but them is no officially recognized "certification' in PICC line insertion or any other specific nursing skill (e.g., peripheral catheter insertion, catheter repair). To date, no nationally recognized accrediting bodies accredit PICC line insertion training programs (291).

State nurse practice acts sometimes limit the ability of nurses to perform PICC line insertions, From 60 to 70 percent of States' nurse practice acts can be interpreted as allowing PICC line insertion by an RN (291). In some States, however, the wording of the acts suggests that such a skill would not be approved, and in a few States, language has been adopted that specifically prohibits nurses from performing PICC line insertions (291). As the use of PICC lines in both home and hospital settings grows, the role of the registered nurse in PICC. line insertion will likely be increasingly recognized at both the State and national level through standardization of training and further modification of nurse practice acts.

[1]Although practice on live subjects is preferable from a quality of training standpoint, it poses legal risks and has been the subject of some controversy among trainers and practitioners (291).

many home infusion providers employ nurses with this skill (364).

Nurse Training and Recruitment—HDIT providers generally look for nurses with extensive experience in infusion therapy nursing (364). Nurses with national certification in certain areas of advanced practice (e.g., IV nurses, critical care nurses, oncology nurses) are more likely to have the skills and experience needed for home infusion practice, although certification is not a guarantee of proficiency in particular skills (291,364). The burden is therefore upon the employer to determine, through testing, practice, and knowledge of educational and training background, whether an individual is proficient in those skills. Providers often recruit hospital nurses who have done infusion therapy in cardiac care units, critical care units, or emergency rooms. Although demand for skilled nurses in hospital settings is high (291), home infusion providers have been successfull in drawing some nurses out of these settings because they offer greater autonomy of practice and, in some cases, more opportunities for career advancement (364).[23] Nurses who specialize in or are skilled in transfusion therapy are also increasingly being sought by home infusion providers as the demand for home blood transfusion expands (box 3-G).

Home infusion companies that provide nursing services through contractual arrangements often must take additional steps to ensure that the nurses are qualified to perform the required services. Contract nurses in visiting nurses associations and home health agencies, or nursing personnel in skilled nursing facilities or other nonhospital institutional settings, may not be familiar with particular HDIT equipment and techniques. To address this

23 Fo,example, one home infusion provider has a five-step "career ladder" for its field nurses based on qualification, expertise, and specialty certification (3). Nurses can move up the career ladder by seeking outside continuing professional education or certification, or by participating in in-house continuing education and certification programs. Five factors considered in the career ladder are: 1) antineoplastic therapy skills/certification, 2) blood transfusion skills, 3) PICC line insertion skills, 4) catheter repair skills, and 5) degree of difficulty of venous across the nurse is capable of handling (3).

Box 3-G-Home Blood Transfusion Services: Special Considerations

Home blood transfusion is a relatively new service in the home infusion therapy market, and it involves intensive, specialized nursing services and careful coordination with suppliers of blood products (e.g., local blood banks). The great risks associated with blood transfusion therapy demand that home providers develop distinct and stringent protocols that address the unique aspects of this therapy.

According to the American Association of Blood Banks (AABB), in-home transfusions should be performed by a registered nurse (RN) with formal training and extensive knowledge and skills relating to IV therapy generally. During the nurse's initial visit 24 to 48 hours before the actual transfusion, a blood sample for type and crossmatch is drawn, carefully labeled, and delivered to the blood bank for compatibility testing. The blood bank must keep an accurate record of the physician's orders, informed consent form, laboratory results, nurse's notes, and a transfusion flow chart for each patient transfused.

On the day of the transfusion, the crossmatched and inspected units of the relevant blood component are picked up by the nurse, who reinspects them for gas formation, streaking, and color. The blood is transported in a quality-controlled insulated cooled container. At the patient's home, the nurse doublechecks the patient's identification and checks each unit to be given for compatibility.

The nurse then reviews the physician's orders, evaluates the patient's condition, administers any prescribed premedications (e.g., antihistamines to avoid mild allergic reactions), and starts the infusion therapy. During the infusion, the nurse monitors vital signs and other signs of the patient's reaction every 30 minutes. once the components have been infused, the nurse discontinues the transfusion, the IV line is kept open, and the nurse remains with the patient in order to watch for adverse reactions and take the 30-minute posttransfusion vital signs. Before leaving, the nurse gives the patient and any caregiver present posttransfusion instructions and collects equipment and contaminated supplies. The nurse returns the day after the transfusion for a followup visit that includes tests such as hemotocrit, platelet count, and coagulation test. In the event of a medical emergency during the transfusion procedure, the patient's residence must be easily accessible. AABB guidelines for procedures in event of a reaction are as follows:

- ***Mild** reaction (e.g.,* rash or itching): The transfusion is stopped and the physician is notified. Usually antihistamines are given and, if the reaction ceases, the nurse will continue with the transfusion while monitoring the patient closely.
- *Severe reaction* (symptoms including rash, increased heart rate, fever, chills): The transfusion is stopped, the physician is notified, and the nurse administers appropriate medications as ordered by the physician. The blood units, administration set, a fresh urine specimen (to inspect for free red blood cells), and a blood sample (to regroup and crosshatch to donor blood, and to perform a Coombs test for hemolytic antibodies) are sent to the blood bank. The nurse stays with the patient until the patient is stabilized, or makes arrangements for transportation of the patient to the hospital.
- ***Life-threatening reaction*** (symptoms include red urine, unexplained bleeding, fever, chills): The transfusion is stopped and another person present contacts the emergency number while the nurse attempts to stabilize the patient (performing resuscitation if necessary). The patient is immediately transported to the nearest hospital.

Under all of the above circumstances, there remaining blood components and administration set are returned to the blood bank for crossmatching. A transfusion reaction report, completed by the nurse, is also required.

Safe disposal of equipment, such as empty blood bags, IV tubing, blood-soaked gauze, needles, and other contaminated objects is a major concern. The nurse must collect all such materials in special biohazard containers and return then-i to the blood bank for proper disposal.

If blood warming in the home is desired either for patient comfort or clinical considerations, only approved electric blood warmers should be used **because** overheated blood can lead to hemolysis (rupture of red blood cells) and protein precipitation.

SOURCES: **American Association of Blood Banks,** ***Home Transfusion** Therapy,* **E.L. Snyder and J.E. Menitove (eds.) (Arlington, VA: American Association of Blood Banks, 1986); American Association of Blood Banks,** *Improving Transfusion Practice: The Role of Quality Assurance,* **S. Kurtz,** *S. S* **ummers, and M. Kruskall (eds.) (Arlington, VA: American Association of Blood Banks, 1989); M. Monks, "Home Transfusion Therapy,"** ***Journal** of Intravenous Nurses* **11(6):389-396, November-December 1988; P.C. Miller, 'Wine Blood Component Therapy: An Alternativ e,"** ***NITA*** **9:213-217, May-June 1986.**

problem, some HDIT companies have highly specialized nurses on staff who train personnel in contracting agencies before they are allowed to serve patients (364).

Delivery Services

In HDIT, all drugs, equipment, and supplies must reach the patient at home in a timely manner. In some cases, a pharmacist or nurse may deliver the supplies directly in the course of a patient visit. Larger providers may deliver supplies to patients' homes in a truck or van. Occasionally, patients may be responsible for collecting their own home supplies (e.g., at each visit to an outpatient clinic).

Most supplies are delivered to patients on a monthly basis in quantities great enough to allow a comfortable margin for the accidental contamination of sterile products by the patient (see box 3-A) and for accidental loss or damage. Additional supplies are brought by visiting nurses as needed.

The drugs themselves must sometimes be delivered more frequently, with frequency depending on the drug prescribed (209). Some require weekly, and some monthly delivery (149). Some parenteral solutions can be stored safely at room temperature or in a refrigerator for days, while others lose their potency after several hours (364) (ch. 2).

For some highly unstable drugs, delivery to the home setting may be unsafe or impractical. For others, increased frequency of delivery from the pharmacy or patient involvement in drug preparation can make home infusion feasible. New technological developments can also affect drug storage life in the home environment. For example, 5-fluorouracil has been found to remain stable for 16 weeks when stored at low temperatures in either polyvinyl chloride drug reservoirs used in electronic infusion pumps or in elastomeric bladder devices (276).

Laboratory Services

Most HDIT requires some degree of laboratory monitoring, either to keep track of the level of infused drugs in a patient's bloodstream or to monitor the patient's bodily reactions to the therapy. Laboratory results are used by the physician and pharmacist to monitor the effects of the chosen therapy and to alter the dosage level or change the therapy when necessary.

Specimens (e.g., blood samples) are usually taken by a nurse during a home or outpatient visit and sent to a laboratory, which reports the results back to the pharmacist and the physician. The pharmacist and the physician, and often the attending nurse, then discuss any changes in therapy that maybe indicated based on those results. It is generally the nurse who implements the prescribed therapeutic changes by reprogr amming the rate of the infusion pump or instructing the patient in a different dosing schedule. Although a few HDIT providers operate their own laboratories, most rely on an outside, independent laboratory for analyses (364).

Coordination Services

Centralized coordination services are critical to HDIT, but the extent and type of coordination and the staff who perform these services vary tremendously among providers. Coordination exists on two levels. First, the various HDIT-related services themselves must be coordinated: the appropriate supplies must reach the patient in a timely manner, the appropriate nurse must visit the home on the appropriate day and time, and emergencies, complications, and patient questions must be dealt with. Second, the infusion services must be coordinated with other services the patient may be receiving, such as basic home nursing, physical therapy, or respiratory therapy. If the patient is receiving separate care for medical conditions not related to the infusion therapy, the HDIT provider must maintain communication with other care providers to ensure that their efforts are not duplicative or in any way harmful to the patient.

Coordination services are often performed by a nurse who acts as case manager (see box 3-C), but some organizations employ nonnurse personnel to perform some of the coordination functions (364). In very small organizations, such as an independent pharmacy provider, the pharmacist may perform some coordination functions as well as pharmacy service (391).

Chapter 4

THE HOME DRUG INFUSION INDUSTRY

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Chapter 4
THE HOME DRUG INFUSION INDUSTRY

Overview

Introduction

The home infusion industry[1] is evolving rapidly, and its characteristics will inevitably have an impact on how Medicare policies regarding home drug infusion therapy (HDIT) play out. This chapter describes some of the more important of those characteristics and their implications.

The chapter first describes the history and growth of the HDIT marketplace and how past Medicare policies have helped to shape it. It then describes the different providers of HDIT and the implications of some of their similarities and differences. Next, the chapter discusses the economic characteristics of the HDIT marketplace: market concentration, ease of entry of new providers into the market, and the scope and scale of services of different providers. Finally, it describes some of the alternatives to HDIT-the choices available to physicians and patients when deciding on the mode and setting of therapy.

Summary of Conclusions

- Federal policies have played a significant role in the development of the home drug infusion industry thus far. Medicare coverage for home enteral and total parenteral nutrition (TPN)[2] (begun in 1977) and the implementation of prospective payment for Medicare inpatient services in 1983 both contributed to the rapid growth of the home infusion industry during the 1980s. Broadening Medicare coverage of home infusion therapies would have a similarly profound impact on the future shape of the industry.
- The diverse nature of providers that constitute the current home drug infusion marketplace present unique challenges for Medicare in developing possible future coverage, payment, and quality assurance policies. Although some providers offer directly the full range of supplies and services needed by HDIT patients, many provide one or more aspects of the therapy by contracting with another entity (e.g., a home health agency (HHA), pharmacy, or medical equipment supplier).
- With the exceptions of hospitals and HHAs that have entered the HDIT business, most providers have limited experience with Medicare beneficiaries due to the current limited Medicare coverage for this therapy. Medicare beneficiaries, because they are on average less well and less capable of performing self-care tasks than younger patients, may require special consideration and additional supportive services.
- Future controls over what companies can charge Medicare patients for HDIT may slow the growth of certain sectors of the marketplace. The revenue growth and seemingly comfortable profit margins that have been enjoyed by the HDIT industry thus far have facilitated and encouraged the entry of new providers into the marketplace, expanding access to home infusion therapy services. The comfortable profit margins are in part due to the fact that these companies have often been able to charge anything short of inpatient charges for similar therapies and still sell their services to hospitals, physicians, and patients.

History and Growth of the Home Drug Infusion Marketplace

The home infusion providers of the 1970s were largely hospitals providing TPN solutions for patients who were individually treated and whose supplies came by way of the hospital pharmacy (288). Technologic advances during the decade were still diffusing; during the period 1970-78, a registry of TPN patients documented a total of 469 such patients discharged home, or an average of only slightly more than 50 patients a year (308). But in the late 1970s, two events sparked the changes that would form the home infusion industry of the 1980s.

[1] Most providers in the home infusion industry offer parenteral nutrition as well as drug infusion therapies.

[2] In enteral nutrition, nutrients are delivered directly into the digestive tract (commonly referred to as "tube feeding"). In total parenteral nutrition, the digestive tract is circumvented and nutrients are delivered directly into the bloodstream.

The first of these events was a decision by Medicare in 1977 to cover TPN solutions and supplies for disabled persons receiving the solutions at home. At the time, the Health Care Financing Administration (HCFA) did not anticipate home TPN to be a major expense; it was expected that only about 10 Medicare-eligible patients per year would need home coverage and that most of these patients would not live long (359). On the grounds that TPN solutions and associated equipment and supplies were a replacement for the digestive tract, HCFA declared these components of TPN therapy to be eligible for reimbursement as a prosthetic device (45).3

The second event was the startup of a new company. In 1979, a private firm, Home Health Care of America, entered the market as a specialist supplier of home infusion equipment, supplies, and services (189). In doing so, it established a model for serving TPN and other patients at home through a nonhospita1 provider. In addition, its rapid growth—with stock prices rising from $7.75 per share in 1979 to $30 per share in 1983 (189,288)-drew attention to home infusion therapy as a potentially profitable enterprise.

By 1983, the home infusion industry was sufficiently developed to draw the attention of investment analysts. A report by the investment research firm Hambrecht & Quist separated the market into three types of players: the large hospital supply companies, which manufactured and distributed home infusion solutions and supplies and had an estimated 24 percent of the market; smaller and more diverse companies with backgrounds in such areas as medical equipment and pharmacy services, which occupied another 22 percent; and hospitals and other providers, including the large hospital management companies, which shared the remainder (288). Therapies included primarily TPN and enteral nutrition, with intravenous (IV) antibiotics and antineoplastics a distant third and fourth (288). That same year, Medicare instituted prospective payment for hospital inpatients, drawing attention to the relative financial benefits of providing nonhospital care.

Between 1983 and 1990 the home infusion industry exploded, from an infant industry with estimated revenues of $265 million to a sophisticated and highly competitive market worth nearly $2 billion (288,307). The industry's high rate of growth continues to be one of its most prominent characteristics. Total market revenues for home infusion supplies and services (including TPN and HDIT) have increased by an estimated 5 to 10 times their 1983 level (34,289,307). Although market analysts disagree somewhat on the exact total revenue volume of the market, all agree that growth rates in the mid-1980s were over 30 percent per year and were still predicted to be over 25 percent in 1991 (307).

One consequence of this enormous expansion has been that new players have been able to enter the market with the expectation of realizing profits fairly quickly. Many of the marketing efforts of home infusion providers during the 1980s were aimed not at drawing patients from competitors but in enlarging the total demand by convincing physicians to refer their patients to home care (364). As the industry growth amply demonstrates, this effort has been successful.

Medicare and the Shape of the Home Infusion Industry

Despite the lack of a direct benefit for HDIT, Medicare coverage and payment policies helped form the fabric from which the home drug infusion industry is made. Probably the most important influence Medicare had on the industry was the decision to cover the products associated with TPN in the 1970s. Because TPN was covered as a prosthetic device, and because only supplies and equipment were covered, supplying TPN and enteral nutrition products became the province of the medical equipment and supply industry. Companies that manufactured the nutritional components (e.g., Baxter) also moved into the retail side of the TPN business, and a few entrepreneurs such as Home Health Care of America actually created high-tech home care businesses around the core of TPN, with its secure reimbursement.

The decision to cover only the products associated with TPN had a secondary effect: it inhibited HHAs, which are service- rather than product-oriented,

3 Medicare does not cover partial parenteral nutrition—i.e., for patients who have a wholly or partially functioning digestive tract-in the home setting.

from entering the TPN business. Although most HHAs rely heavily on Medicare business, the patients they serve are traditionally and by definition relatively dependent on nursing and assistive services; Medicare patients must be homebound and require periodic skilled nursing visits to be eligible for home health benefits (see ch. 6). In contrast, the lack of Medicare coverage for services associated with TPN meant that most TPN patients were quite independent. TPN patients had to be able to self-administer their solutions unless they were also homebound and thus eligible for some supplementary home health benefits. Thus, the history of Medicare reimbursement for infusion therapy (i.e., TPN) has resulted in home infusion therapy equipment and supplies, on the one hand, and home nursing, on the other hand, being entirely distinct from one another.

As providers of home infusion therapy looked for new sources of revenue, they began to apply their expertise in pharmaceutical preparation and equipment/supply distribution to drug therapies. Private insurers began reimbursing for some of these therapies when convinced of their ability to avoid hospital-related charges by covering self-administered home therapy. Medicare began covering a few speci.tied drugs under the durable medical equipment benefit when those drugs were used in an infusion pump (see ch. 6), further reinforcing the relationship between home infusion therapy and the medical supply and pharmaceutical industries.

With the continually expanding opportunities for increasing revenue through providing new kinds of home infusion therapies, the growing industry has attracted providers from all directions. Hospitals, physicians, pharmacists, HHAs, dialysis providers, and a diverse variety of other health care providers have branched into the home infusion therapy business. Some provide a number of different components of HDIT; some provide only one or two components. Each provider type brings with it its own particular bias in the organization of therapy, the kinds of patients it serves, and its relationships with other providers of the therapy. The following section describes some of these provider-specific characteristics.

Home Drug Infusion Providers

HDIT providers vary in three basic ways:

1. *Home-based v. center-based models—Home-*based models provide all aspects of therapy in the patient's home. Center-based providers usually train patients for basic self-care (e.g., dressing changes), but provide needed skilled nursing services (e.g., catheter site changes) and delivery of supplies to the patient in an outpatient center.
2. *Pharmacy-based v. nursing-based models—*Most home infusion therapy has historically been pharmacy-based-i.e., the focus has been on pharmacy-related services, with nursing services provided or contracted as needed. For patients capable of full self-care, these have been only occasional nursing visits. As more persons with multiple nursing needs (e.g., persons with AIDS)[4] have been served, as more complicated therapeutic regimens have been transferred to the home setting, and as HHAs have diversified into infusion therapy, more nursing-based models have arisen. (Examples of the different staffing responsibilities between the two models can be found in chapter 3, box 3-B).
3. *Ownership and orientation—The* ownership, parent company, and original mission of the infusion provider can dramatically affect how it provides services, what it offers, and who it serves.

Seven basic types of providers, and their individual strengths and weaknesses, are described below.

Hospital-Based Providers

The intensive nature of HDIT and the fact that it is often an extension of, or a replacement for, hospital care has made the service attractive to many hospitals. For some, providing home infusion services is simply an extension of the services of a pre-existing hospital-based HHA; for others, it is an entirely new venture into home care (see box 4-A). The total number of hospitals currently providing HDIT services, either through special outpatient infusion therapy units or their own HHAs, is unknown. However, recent survey data suggest that

[4] Acquired immunodeficiency syndrome.

Box 4-A—Example of a Hospital/Based Provider: Anne Arundel General Hospital Outpatient Intravenous (IV) Therapy Services

The Anne Arundel General Outpatient IV Therapy Services Program, started in 1978, is an outpatient department of Anne Arundel General Hospital, a 330-bed facility near Annapolis, MD. The hospital, which previously had been discharging some patients in need of home infusion therapy to proprietary providers, decided to start its own program because none of the proprietary providers offered antibiotic therapy. As of 1990 the program provided only antibiotic therapy, but it planned to begin offering IV antineoplastic therapy, pain management, and total parenteral nutrition.

All patients are referred from the parent hospital. Most start their infusions as inpatients and receive their training while still in the hospital The few who start as outpatients are trained in the outpatient center. Because the typical course of IV antibiotics requires infusions two to three times a &y, most patients administer the drugs themselves at home and come into the outpatient center several times a week to see a nurse and clinical pharmacist and at least once a week to see a physician. During these visits, patients pick up their drugs and supplies, receive any required skilled services (e.g., catheter site changes), and are checked for possible complications of therapy. If a patient is homebound, care is provided through the hospital's hospice/home health department but is still coordinated by the outpatient IV therapy team. Home health nurses involved in care of homebound patients are trained by the center staff. All staff involved in patient care meet on a weekly basis to review each patient's progress.

SOURCE: Anne Arundel General Hospital Outpatient Intravenous Therapy Services, Annapolis, MD, site visit by OTA staff, Oct. 25, 1990.

a growing number of hospitals are providing these services either directly or indirectly. According to the American Hospital Association, 31 percent of nonfederal hospitals provided some kind of home health services in 1988 (10). A 1990 survey of hospitals with home care programs[5] found that 62 percent of these hospitals directly provide home IV therapy and 23 percent provide home medical equipment (197). By comparison, a 1982 survey of 243 Medicare-certified hospital-based HHAs[6] found that only 29 percent offered some kind of home IV therapy (120).

An advantage to hospitals of developing their own home infusion programs is the ability to keep patients within the hospital-based system, rather than losing revenues to other providers once a patient is discharged. The on-site physician and pharmacy resources of hospital-based home infusion programs may also confer some advantages on these programs. However, HDIT is not simply a transplantation of hospital infusion to a home setting; it requires additional skills on the part of nurses and pharmacists, and it often requires much closer communication between pharmacists and patients than hospital pharmacists may be accustomed to (see ch. 3). Additionally, hospital-based programs may raise concerns about anticompetitive behavior if hospital patients are routinely referred to the hospital's own program rather than enabling them to choose among competing providers in the community. Large hospitals are generally in a better position to implement a successful HDIT program because they are more likely than small (e.g., under 200-bed) hospitals to have a sufficient patient base and the specialized staff needed to support such services (364).

Home Health Agencies

HHAs view HDIT as an extension of the home nursing and associated services they provide. HHAs may opt to become full-service HDIT providers themselves, either acquiring necessary pharmaceutical expertise in-house or contracting outside for pharmacy services (see box 4-B). Alternatively, an HHA may act as a contractor to another provider to supply only the nursing (or nursing and equipment) components of a home infusion service. For example, an HDIT provider located in a major city but with patients in a more distant town might contract with an HHA in that town to provide nursing and other infusion-related services to local patients. Although no hard data are available, the National Association for Home Care (NAHC) estimates that at least 75 percent of HHAs nationally are involved at some level in home infusion therapy. About half of these act as primary providers, while the remain-

[5] **The survey was mailed to 1,983 hospitals with home care programs in May 1990. The response rate was 41 percent (197).**

[6] **The response rate was 73.7 percent.**

Box 4-B—Home Health Agency-Based Providers: Two Examples

Visiting Nurses Association of Los Angeles

In 1986, the Visiting Nurses Association of Los Angeles (VNA-LA), a Medicare-certified home health agency (HHA), expanded its business to include home infusion therapy by entering into a partnership with an established pharmacy, which provides clinical pharmacy expertise and parenteral drug compounding services. VNA-LA viewed home infusion therapy as a potentially profitable enterprise, especially given the high number of AIDS patients they were already serving at the time.

Since the partnership was formed, VNA-LA has become a key competitor in the Los Angeles home infusion therapy market, marketing its services to abroad range of providers including physician group practices, hospitals, and local health maintenance organizations. Unlike some other HHA-based providers, VNA-LA provides directly the full range of drugs, supplies, and services.

Handmaker Home Health Services, Tucson, AZ

Handmaker Home Health Services, Inc., also a Medicare- certified HHA, is an offshoot of a Jewish geriatric center. For the last 9 years, Handmaker has provided home infusion therapy services to patients referred from its geriatric center, from a nearby local hospital, and from local physicians familiar with its services. The majority of Handmaker's business is antibiotic therapy, although it has provided antineoplastic therapy and parenteral nutrition on occasion. All nursing and coordination services are provided by a single staff nurse specialist. Most parenteral solutions and associated supplies are obtained from a nearby hospital pharmacy whose staff provide 24-hour pharmacy coverage. Durable medical equipment (e.g., pumps) are obtained through an outside supplier.

Handmaker's home infusion therapy business is very small---no more than 25 patients at any given time-due to limited staff and the intensity of services required by most of its patients. Almost all clients are over 65 years of age, all are confined to their homes, and few of them are capable of self-administering; thus, the nurse must make a home visit for each drug administration.

SOURCES: L.J. Terry and S.F. Grigsby, "Visiting Nurse Home Pharmacy: A Successful Home Pharmacy Venture," *Caring, May* 1990, pp. 28-32; site visit by OTA staff to Handmaker Home Health Services, Inc., Tucson, AZ, May 2, 1991.

der participate as subcontractors to other providers for a limited portion of home infusion therapy services (97).[7]

Although a growing number of Medicare-certified HHAs are proprietary, most are still non-profit (e.g., many visiting nurses associations) and some are associated with government agencies (e.g., public health departments) (table 4-1) (372). Consequently, the kinds of patients HHAs see may differ considerably from those seen by other home infusion therapy providers. Based on conversations with providers, it appears that HHA infusion patients are more likely to have additional disabilities (e.g., be homebound) and less likely to have private insurance than the infusion patients seen by other providers (364). Medicare-certified HHAs see Medicare patients, while other HDIT. providers may not.

A strength of HHAs is that, since they provide a variety of home services in addition to infusion therapy, they are in a good position to coordinate services for patients with multiple health problems. They already have systems in place for providing medical equipment, and their experience with treating patients at home may translate into a greater base of expertise for patient evaluation and monitoring in the home setting and identification of the kinds of environmental and emotional barriers that can impede effective home care.

A drawback for HHAs providing HDIT is that they usually have no in-house pharmacy services, making the availability of 24-hour communication with pharmacists familiar with a particular patient's condition and treatment of greater challenge and concern. In addition, some HHAs lack the specialized nursing skills needed to support HDIT services. A few HHAs do specialize in HDIT and have the full range of services in-house (347).

Community Pharmacies

HDIT's attraction for community pharmacies lies in the ability to extend the scope of pharmacy services beyond those of the traditional 'comer drug

[7] **Based on informal surveys conducted in 1990 by NAHC (97).**

Table 4-I—Medicare-Certified Home Health Agencies (HHAs) by Ownership, Selected Years, 1974-90

Type of HHA	Number of HHAs			
	1974	1979	1989	1990
Visiting nurses association	532	528	478	478
Combined government and voluntarary	52	65	45	45
Official (government)	1,298	1,298	974	952
Rehabilitation facility-based	NA	NA	8	8
Hospital-based	269	363	1,466	1,508
Skilled nursing facility-based	NA	NA	102	102
Proprietary	NA	197	1,870	1,918
Private nonprofit	NA	461	714	710
Other[b]	178	61		NA
Total	2.329	2.973	5,721	5,721

NOTE: NA - not applicable. See footnote b.
[a]A voluntary organization (e.g., a visiting nurses association) that receives some operational funding from government sources.
[b]In 1974, "other" includes rehabilitation facility and skilled nursing facility-based HHAs, proprietary HHAs, and Private nonprofit HHAs. In 1979, "other" includes rehabilitation facility and skilled nursing facility-based HHAs. In 1989 and 1990, each type of HHA is counted as a separate category.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, Office of Statistics and Data Management, April 1991.

store." Pharmacists may view the expansion into home infusion services as not only a new source of revenue but a way to enhance the pharmacy's reputation as a health care provider (364). Some pharmacies are independent providers of home infusion therapy; others operate their home infusion service as a franchise of larger home infusion company (see box 4-C). Pharmacy-based home infusion providers may contract with other providers (e.g., an HHA) for the nursing component of the service if they do not have skilled nurses in-house. Alternatively, a community pharmacy may provide only the drugs and pharmaceutical services under contract to another home infusion provider.

Community pharmacies, like HHAs, have the advantage of being familiar, local sources of services. They may be an especially valuable source of HDIT in small communities with no alternative local providers, where they often cooperate with local hospitals or nursing agencies to provide the full spectrum of necessary services (see box 4-C). They may also be in a better position than larger providers to provide continuity of care, since community pharmacists may have ongoing familiarity with their patients' health care needs.

On the other hand, few such pharmacists routinely employ nurses, and many may not see a sufficient number of patients to make the startup and ongoing costs associated with providing high-quality infusion services feasible. Another disadvantage is that most existing community pharmacists entered practice before most pharmacy schools routinely trained students in the variety and depth of skills necessary for home infusion therapy (see ch. 3). Such pharmacists must receive substantial additional training before they are qualified to provide these services.

Medical Equipment Suppliers

Many hospital-based agencies, HHAs, and community pharmacies that provide home infusion therapy also provide medical equipment and supplies as part of their broader array of services. Conversely, companies that specialize in providing medical equipment and supplies may expand their services to include home infusion therapy. They do so either by acquiring nursing and pharmaceutical expertise in-house or by contracting with other home infusion providers to supply patients with the drugs and services necessary for their conditions (see box 4-D).

The role of contractor to provide deliveries directly to the patient is a natural one for many equipment suppliers, since it is a relatively minor extension of services they already provide. Acquiring sufficient in-house expertise to become a full-service home infusion therapy provider is a much larger venture; it may require a greater investment in new areas of expertise for medical equipment suppliers than for most other providers expanding into this service area. Some medical equipment suppliers have entered the home infusion marketplace by offering coordination services.

Box 44—Example of a Pharmacy-Based Provider: Vital Care, Inc.

Vital Care, Inc., based in Livingston, AL, is a network of parenteral and enteral service suppliers locally owned and operated by independent community pharmacists. The network began with three sites in 1986 and by 1990 had grown to 61 sites in Alabama, Mississippi, Florida, Kentucky, Georgia, Tennessee, and Louisiana. Each franchise operation is capable of providing the full range of home infusion therapies, including enteral and parented nutrition, antibiotic therapy, antineoplastic therapy, pain management, and hydration therapy.

Vital Care, Inc. provides franchisees with a complete initial training program at the franchise location. It also offers centralized billing and collection, patient training materials, quality assurance standards, operation protocols and forms, phone consultation, ongoing training in home infusion techniques, and technical assistance in a variety of other areas.

All drugs and supplies required for therapy are provided in-house. Each site has at least a registered pharmacist, and some have registered nurses on staff. Generally, if nursing services are required, they are provided by local home health nurses under contract who have been given additional training by the Vital Care nurse or pharmacist.

SOURCE: J. Hindman, Director of Marketing, Vital Care, Inc., Livingston AL, personal communication, Aug. 30, 1990.

Specialty Home Infusion Therapy Providers

Whatever their origins, a number of organizations have specialized in home infusion therapy to the extent that they have become independent full-range providers of this service. Most of the largest players in the national marketplace fall more or less into this category; nearly all are for-profit companies. Some are subsidiaries of a larger corporation, while others are smaller companies that specialize primarily or exclusively in home infusion therapy (see box 4-E). Some are national companies that operate through branches in various States and localities, while others serve a more limited geographic area. The primary characteristic of all of these HDIT providers is that they provide most or all of the nursing, pharmacy, coordination, and equipment-related services themselves. (Laboratory services are still usually performed in outside clinical laboratories.)

Box 4-D—Example of a Medical Equipment Company-Based Provider: Mediq, Inc.

Mediq is a medical equipment supply company that branched into the home services market via respiratory therapy in 1975, providing the equipment and supplies as well as the respiratory therapist and other consultative services. In 1984 the company branched into infusion therapy on a similar model. Mediq provides the equipment and medical supplies, trains health personnel in their maintenance and use, and coordinates the services of all entities involved in home infusion therapy. It contracts with or helps to coordinate the services of independent and hospital pharmacies for pharmaceutical supplies and services (e.g., require the pharmacist to be on call 24 hours a day). Local nurses and patients are trained in home infusion therapy techniques by Mediq personnel. Mediq's own specialty nurses are on call and go to patients' homes should problems arise.

The company's goal is to provide continuity of care to patients by utilizing existing resources in the community. It believes its model maybe especially appropriate in smaller communities where it makes more sense to utilize local providers than to have a large specialist company.

SOURCE: L.M. Ferry, Universal Management Systems, Inc., Newton Square, PA, personal communication, Oct. 22, 1990.

The major strength of providers in this category is their ability to coordinate in-house three central HDIT services: nursing, pharmacy, and supplies. Specialization may also enable such providers to operate at a level of economic efficiency that providers with smaller caseloads and other functions cannot match. Potential drawbacks of these providers are that they may not find it efficient to provide services in areas of sparse population, and since most such companies are for-profit they may be more reluctant to provide charity care than smaller organizations with broader missions and local reputations to maintain. Also, companies that specialize in home infusion therapy may be poorly positioned to coordinate the diversity of other home care services that some patients—for example, homebound elderly patients-need.

Physician-Owned Providers

Some physicians (or groups of physicians) have started their own home infusion therapy services outside of the hospital setting. These providers may

Box 4-E-Example of Home Infusion Therapy Specialty Provider: HMSS, Inc.

HMSS, Inc. is a specialized home infusion company with ***28*** locations in 15 States (as of 1989). The majority of its business (55 percent) is in parenteral antibiotic therapy, with the remainder in total parenteral nutrition (20 percent) and other therapies (25 percent). HMSS sites typically provide skilled nursing, pharmacy, and medical equipment and supplies in-house, with laboratory and general home health nursing services provided under contract. All billing is done through the HMSS central office in Houton, Texas.

Although only a small proportion (7 percent) of the company's total revenues nationally are from Medicare and Medicaid, individual sites may see a greater proportion of Medicare patients. Some HMSS sites have sought Medicare home health agency certification, while others serve Medicare home health patients under contract to certified providers, For example, 30 percent of patients seen by a Medicare-certified HMSS site in Phoenix, AZ have Medicare coverage.

Referrals come mostly from national contracts with national health care or insurance companies and from local physicians to whom HMSS branches market their services. HMSS targets its marketing efforts to surgeons, general and family practitioners, and infectious disease specialists.

SOURCES: ***Home Health Line*****, vol.** ***XVI*****, p. 109, Mar. 27, 1991; HMSS, Inc., Phoenix, AZ, site visit by OTA staff, May 3,1991.**

Box 4-F—Example of a Physician-Based Outpatient Infusion Therapy Provider: Infections Limited, P.S.

Started in 1981 **as part** of a clinical investigation of the use of the antibiotic ceftiaxone for the treatment of ostomyelitis, Infections Limited, P.S., is now a full-fledged outpatient parenteral antibiotic program offering a wide range of antibiotic therapies. The program is based in the office of a group of five infectious disease specialists who employ five intravenous (IV) therapy nurses, a pharmacist, a pharmacist technician, microbiologists, and other support personnel.

Patients are trained either in the hospital or in the outpatient center by an IV nurse from the center. They receive all skilled services in the outpatient center, where they are seen by an IV nurse every 3 to 4 days and by a physician at least weekly. Most patients self-administer their antibiotics at home, although a few prefer to come into the outpatient center to have them administered. Medicare patients are only infused in the outpatient center because the cost of the drugs is not covered if they self-administer. The outpatient center is open 7 days per week and staff are available by phone 24 hours a day.

Currently, the program serves an average of 30 patients each day. Patients are referred either by one of the group's own physicians, all of whom consult at local hospitals, or by other physicians who are familiar with the program's services.

SOURCE: A.I). Tice, "An Office Model of Outpatient Parenteral Antibiotic Therapy," ***Reviews of Infectious Diseases*** **13(Suppl. 2):S184-188, 1991.**

specialize in therapies relevant to their area or speciality practice. For example, an oncologist-owned group might provide primarily home antineoplastic therapy and pain management, while a company owned by infectious disease specialists provides mostly antibiotic therapy (see box 4-F). Some groups may specialize in treatment for a particular condition, such as Lyme disease (see below). Alternatively, physician-based companies may provide a wider range of infusion therapies and market their services to a large number of physicians.

Like other providers, the range of services that physician-owned companies provide in-house varies. Some may provide only the physician services directly; others also have in-house pharmacy and nursing. Physician-owned companies may be either office-based, where patients visit the office or center for most of their HDIT needs; or home-based, where nurses provide all needed services at the patient's home.

Potential advantages to physician-owned and -operated infusion companies include increased communication between physicians (both inside and outside the company) and other health professional staff, and increased frequency of physician contact with patients. Physician-owned providers also enjoy the potential for local market monopolization through self- and peer-referral networks. Although these providers might view such monopolization as an advantage, payers might not (see ch. 7).

Box 4-G-Specialized Home Infusion Therapy Providers: Cystic Fibrosis Fondation Home Health Services, Inc.

The Cystic Fibrosis Foundation (CFF) entered the home infusion therapy business in January 1990 as a nonprofit organization that provides intravenous drugs and supplies to cystic fibrosis patients on home therapy. CFF seined approximately 300 patients in its first year of operation, averaging about 20 patients at any one time.

CFF provides pharmacy services in-house and mails the drugs overnight to its patients. Nursing services are provided by local nursing agencies under contract, and physician consultation is available from physician specialists in the national office. Transportation, which is used for marketing and for travel to inservice training at local nursing agencies, accounts for a significant proportion of the program's costs. In some large cities where they expect to have at least some patients, staff do inservice training prospectively at visiting nurses associations or other home health agencies (HHAs); in other cases, they must travel to a previously unidentified HHA in a new city after a patient has been identified.

Because cystic fibrosis patients are the only clients, CFF's inservice training is more disease-focused than that provided by other home infusion companies. Local nurses are trained not only in infusion technique but also in how to monitor patients for other potential conditions not immediately related to infusion therapy that might signal changes in the well-being of patients or in the course of their disease.

SOURCE: D. Paxton, Vice President, Cystic Fibrosis Foundation Home Health Services, Rockville, MD, personal communication, Dec. 4, 1990.

Other HDIT Providers

Although most HDIT providers fall into at least one of the above categories, other types of organizations may also expand their services to include HDIT if they see sufficient demand in their service population. The Cystic Fibrosis Foundation, for example, in 1990 began providing home infusion therapy to patients with this disorder across the country (see box 4-G). The advantage for patients in this case is the provision of low-cost services that are coordinated by individuals with in-depth knowledge about the underlying disorder. Disadvantages are that the scope of services may be limited and there may be logistical difficulties in providing services to patients in distant locations.

One very recent example of a specialized provider is Women's Homecare, Inc., a network of physician-owned women's home obstetrical and gynecological health care providers (164). This new company is a joint venture of Tokos Medical Corp., a company that manufactures home uterine monitoring devices and operates 70 company-owned home uterine monitoring locations nationwide, and T2 Medical, Inc., a national company that owns or manages approximately 145 physician-based home infusion therapy providers. Women's Homecare locations will combine home uterine monitoring and associated IV therapies to serve high-risk obstetric patients. In the future it may branch out to provide home IV antibiotic therapies for a wider range of gynecological indications (164).

Another specialized physician-based provider, Preferred Physicians Infusion Center, Inc. (PPIC), is the result of a recent joint venture between the national home infusion company Preferred Homecare of America, Inc. and a local physician specialty group in Monmouth County, NJ (162). PPIC, a clinic-based infusion center, specializes in IV antibiotic therapy for patients with Lyme disease. It was developed to serve the growing need for such therapy in Monmouth County, which reportedly has the Nation's highest incidence of Lyme disease (162).

Economic Characteristics of the Home Drug Infusion Marketplace

Market Concentration

The home infusion market is characterized by a few large firms that dominate the national market, a number of midsized companies that individually have very small national market shares but strong shares in certain regions of the country, and many small providers. Table 4-2 presents one estimate of the relative national market shares of eight of the largest home infusion providers in 1988. Caremark had by far the largest share of any single provider in that year, with other major providers holding shares ranging from 1 to 6 percent. Between one-third and two-thirds of the total market, on the other hand, was in the hands of small providers, most of whom individually had less than 1 percent of the national market (289,307).

Table 4-2—Relative Share in the Home Infusion Market of Eight National Proprietary Providers, Estimated 1988 and Projected 1991[a]

Company	1988	1991
Caremark	37.3%	29.3%
New England Critical Care[b]	4.1	7.1
Home Nutritional Servfces	4.0	4.2
HMSS	3.0	4.7
National Medical Care[c]	2.5	4.2
Care Plus[b]	1.9	2.4
Continental Affiliates	2.8	2.2
T[2 d]	2.8	2.7
Other	41.9	43.3

[a]Includes revenues from total parenteral nutrition.
[b]In February 1991, after these projections were made, New England Critical Care merged with Care Plus to form Critical Care of America, Inc.
[c]Includes revenue projections for Infusion Care, acquired by National Medical Care in January 1989.
[d]Based on estimated revenues of the partnerships it manages.

SOURCE: Prudential-Bache Securities, Inc., New *England Critical* Care Company *Report* (New York, NY: Prudential-Bache Securities, Inc., 1990).

Consolidations among the larger providers and new entry by small providers have been the rule in the past few years. Caremark, for example, is the product of two major acquisitions of other companies during the 1980s by Baxter-Travenol, a major manufacturer of medical equipment and supplies. Recently, New England Critical Care purchased Care Plus, a move which will most likely position it solidly in second place behind Caremark (161).

At the other end of the spectrum, a growing number of community pharmacists are expanding into the home infusion business, as evidenced by the rapid growth of pharmacy franchise companies. Vital Care, Inc., for example, expanded its number of franchise pharmacies from 3 in 1986 to 61 in 1990 (see box 4-C) (158). O.P.T I.O.N. Care, which has been growing at a rate of 20 or 30 franchises per year for the last 4 years, currently has 182 franchises throughout the country (272). The Parenteral and Alimentation Provider's Alliance, an association of independent pharmacies that have cooperative group purchasing arrangements, increased in size from 3 participating pharmacies in 1987 to 30 in 1990 (109).

As with pharmacies, HHAs view home infusion as a natural and profitable expansion of their businesses. For most HHAs, infusion is only a small part of their total home nursing and supply business, but where HHAs are large even this small proportion may amount to a large total number of patients and a significant source of revenues. For example, Kimberly Quality Care, a large home health services provider with 409 branches throughout the country,[8] served 2,941 home infusion therapy clients[9] in 1990, but these patients made up only 0.7 percent of its total national client population for that year (333).

Providing nursing services for home infusion patients has been a natural extension of the general home nursing done by HHAs, and most HHAs have probably now served at least some such patients. A number of HHAs, however, are establishing teams of IV nurses and even in-house pharmacies to become more comprehensive providers of infusion services, placing them in direct competition with the home infusion speciality companies (see box 4-B) (338,347,390). In some cases, high concentrations of AIDS patients in the HHAs' vicinities have served as a catalyst for expansion into full-scope home infusion therapy services (163,338).

Hospital-based home infusion services are common as well, although there seems to be little indication that these providers are increasing in number as fast as other market participants (307, 364).

Although individually each of the many small home infusion providers represents a negligible share of the total national market, they can have a substantial share of the local markets in which they operate. Hospitals, HHAs, and community pharmacies are often locally well-established and well-known, and they may be successful in luring many infusion patients-and the physicians who refer them-away from the larger national companies. Some companies have capitalized on this local advantage. Vital Care and O. P.T.I.O.N. Care, for example, concentrate on marketing their franchise operations to community pharmacies in small- to medium-sized towns, where patients and physicians often have strong loyalties to the familiar local pharmacies and where the advantages of the larger, more centralized national companies are lessened (158,272).

[8]As of January 1990, 170 of these branches offered full-service home infusion therapy services (333).
[9]Excludes enteral nutrition patients.

Providers' Scale and Scope of Services

Although small providers often have the advantage of local reputation, the large national home infusion providers have the advantages that accompany economies of scale. Large companies with high patient volume can afford to invest in specialized personnel, so that nurses with particular expertise (e.g., in antineoplastic therapy) can be assigned to patients with relevant problems. In addition, large companies can recruit young pharmaceutical and nursing staff with recent clinical and infusion experience, eliminating much of the need for re-education that some retail pharmacists and home care nurses must undergo before entering the infusion therapy field (364).

The centralized billing capability of many large providers also has distinct advantages; since home infusion therapy is still a relatively young field, many insurers do not have clear rules regarding how and what to pay for, and those that do differ in their guidelines and billing requirements (364). Personnel who can devote their full time to learning the intricacies of different payers' policies are probably much more successful in getting the claims paid.

The advantages that attend some of these economies of scale explain the popularity in the industry of organizations that fulfill some of these functions. Pharmacy franchises and purchasing associations in particular example the match between local businesses and access to central billing, educational, and marketing expertise.

The home infusion industry may also have some economies of scope. Few providers offer only home infusion services. The great majority branched into home infusion services or products as an extension of previous business in pharmaceuticals, medical supplies, home nursing, or other health care services. For large providers, such as Caremark, the other business of the parent company-in this case, supply manufacturing-can provide low-cost inputs into the infi.mien business, while the experience in home infusion can in turn provide ready feedback on technological innovations in supplies. For small providers, such as HHAs and community pharmacies, the basic business of home nursing, retail pharmacy, or medical equipment supply also provides the stable source of revenue that could be endangered by low and volatile patient volume in the infusion business.

The advantages of providing complementary services are often great enough to encourage infusion-only providers to branch into related areas. For example, Abel Health Management Services, Inc., a privately owned firm in New York, began as a small home infusion company in 1985. Its separate divisions now include not only a pharmacy and an infusion nursing service but also a medical equipment supply company, a long-term nursing care service, and a diagnostic laboratory (3).

Ease of Entry Into the Market

During the 1980s home infusion was a fast-growing industry, and the prospect of profits has drawn a multitude of new providers. In hard immediate dollars, the costs of starting up a home infusion business have been relatively low for many small providers; some companies have reported startup costs of as little as $100,000 (153). Contracting for or cooperatively providing services not provided in-house (e.g., pharmacy or nursing services) lowers fixed startup costs and is undoubtedly why such arrangements are common among smaller providers. (Because of the travel costs associated with home delivery and nursing, however, even large companies often contract for some services in areas distant from their central facilities.)

The greatest startup costs for most new providers are probably the acquisition of resources (i.e., personnel and equipment) and the costs of marketing the service to get referrals (364). Relevant pharmacy, nursing, and management expertise in home infusion therapy differs from that in other areas of health care, and it must be acquired either by hiring (or consulting with) personnel who already have it or by spending the money to train those who do not. Marketing costs can be high, especially if the groundwork has not been laid by existing home infusion providers and the new entrant must take on the task of educating the physicians and hospital personnel regarding the possibilities and advantages of home therapy. The importance of expertise and marketing as components of startup costs mean that ways to reduce these costs-e. g., through purchasing marketing and expertise through a franchise arrangement-are a mechanism to ease entry into the market.

The prospect of profits to be made in the industry have attracted new entrants despite some of these startup costs. Because home infusion is still largely

Box 4-H—Alternatives to Service-Intensive Infusion Therapy

The traditional alternatives to infused drugs are oral drugs, which when appropriate are usually both simpler and cheaper to administer. When parenteral drugs are preferred, the reason is usually greater drug effectiveness; the usual reason for prescribing intravenous antibiotics, for example, is that oral antibiotics have proven (or are expected to be) insufficient to get rid of the infection (see ch. 2).

New, more potent forms of oral drugs, however, can sometimes compete with intravenous (IV) drugs. For example, oral ciprofloxin, one of the recently developed fluoroquinolone antibiotics, is often effective in treating osteomyelitis caused by certain organisms (126). The drug is, with good reason, regarded by the home infusion industry as a competitor to IV antibiotics for this use (289).

Changes in equipment technologies have broadened the range of drug infusion alternatives available for some conditions, HDIT, as described in this report, uses external infusion devices and is often service-intensive. For antineoplastic therapies, in which total liquid drug volume is small, tiny infusion pumps that are surgically implanted in the body, and replenished with the drug at the physician's office, are an alternative to similar drugs administered by an external infusion pump that the patient must operate.

Other technological advances may result in alternatives to HDIT in the future. Medicated patches that gradually release a drug absorbed through the skin, for example, could replace other forms of administration for some drugs. A transdermal patch for an analgesic, fentanyl, was recently introduced in the United States for management of pain in cancer patients, offering an alternative to IV analgesics for some patients (275). Slow-release implanted drugs (e.g., the recently approved contraceptive Norplant) could offer another, similar "infusion" alternative to the service-intensive kind of HDIT described here.

viewed as an alternative to hospital care, and because hospital charges are relatively high, home infusion providers have probably often been able to charge prices considerably higher than their actual costs (see ch. 6). Payers have apparently been relatively insensitive to differences in prices among home providers as long as these providers can convince payers that total home charges will be less than total hospital charges. Lower profit margins, as payers become more discriminating, may discourage some new entrants.

Alternatives to HDIT

The demand for HDIT and the growth of the industry depend in part on the existence of alternatives. Some alternatives take the form of new, less service-intensive ways administering the therapy (box 4-H). When service-intensive infusion therapy is necessary, however, there are four basic alternatives to home care as the site of therapy: hospitals, outpatient clinics, physicians' offices, and nursing homes.

At present, the home infusion industry still views its main "competitors" as hospitals and has devoted most of its efforts to wooing patients away from these institutions. One result has been to encourage some hospitals to enter the home infusion market themselves in order to keep their patients-and the associated revenues—within the hospital's domain. Despite this incentive, and despite the relative advantages of having in-house trained clinical pharmacy and infusion nursing staff, hospitals appear to be less successful than some other types of providers in making the transition to providing HDIT unless they have previous experience with home care (e.g., an in-house HHA), or they can successfully combine HDIT with hospital outpatient-based nursing services (15,177,307).

Other sites of care, however, may develop as future competitors. Physicians' unwillingness to refer patients away may result in increasing amounts of infusion care being provided in physicians' offices and outpatient clinics, where concomitant billable physician visits can also take place (see box 4-F). These sites have the advantage of greater professional oversight of infusion and lower provider costs associated with travel. Because physicians control referrals, however, these arrangements-and others where physicians are co-owners of the HDIT providers-can result in market monopoly, as mentioned above.

In a typical outpatient HDIT setting (either a hospital outpatient center or a physician's office), patients come to the center for the professional services they require (e.g., peripheral catheter rotation, laboratory work) and perform the remainder of

tasks (drug administration, catheter flushing) by themselves at home (15,335) (see box 4-F). An advantage to this type of arrangement is that outpatient settings provide greater access to the professional resources required to address specific therapy-related problems than in the home setting. For example, if a nurse in an outpatient center notices site imitation in a patient, he or she can immediately involve other health professionals (e.g., a physician or clinical pharmacist) in determining an appropriate course of action to treat the problem and avoid serious infection.

Another advantage to the outpatient clinic as the setting for routine professional services for HDIT is health system cost. For patients who are ambulatory, who only need to be seen professionally every several days, and who live reasonably near an outpatient center, extra professional costs associated with home visits (transportation, reimbursement for travel time, additional paperwork, and interprofessional communication) can be avoided.[10]

Nursing homes may also become more significant players in providing infusion therapy if cost constraints imposed by health insurers make this setting relatively attractive. Some health maintenance organizations, for example, refer infusion patients to nursing homes if they expect the costs in this setting to be less than home care costs (389).

Some nursing homes may be better equipped to provide the required services than others. Currently, nursing home patients who require infusion therapy usually have to be transferred back to an acute-care hospital because the nursing facility lacks the resources to provide skilled infusion therapy services. A 1985 study of one nursing home found that 17 percent of its patients had to be admitted to the hospital during a l-year period (344). The study estimated that one-third of these transfers could have been avoided if the nursing home had had the staff and other resources required to administer infusion therapy (344).

Some skilled nursing facilities (SNFs) have responded by implementing infusion therapy training programs for their staff and establishing special infusion therapy units to handle the needs of patients who would otherwise have to be readmitted (62). Other SNFs purchase the specialized services of home infusion companies, who send nurses and/or pharmacists to the facility as much as they would if it were the patient's own home (see ch. 4). In some cases, home infusion companies themselves train staff at the nursing facility to perform skilled tasks associated with infusion therapy (364). Home infusion companies may even operate SNFs (158).

[10] An apt analogy can be found in recent changes in Medicare policy regarding mode of service delivery for home dialysis patients. In 1990, HCFA stopped paying for home health aide services for home dialysis patients after Congress agreed that dialysis services were more cost-effective when delivered in an outpatient center (Public Law 101-239).

Chapter 5

QUALITY ASSURANCE IN HOME DRUG INFUSION THERAPY

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Chapter 5

QUALITY ASSURANCE IN HOME DRUG INFUSION THERAPY

Overview

Introduction

As described in previous chapters, home drug infusion therapy (HDIT) is a high-technology, invasive service that can pose considerable risk to patients. Complications of therapy are potentially more serious in the home than in the hospital, because health personnel are not be immediately available to recognize and treat them. HDIT is further complicated in that it requires the coordination of multiple services (medical, pharmacy, nursing, laboratory, and supply) that are often provided by separate entities. If Medicare were to provide coverage for HDIT services, it would want to implement some measures to protect beneficiaries from inappropriate and substandard care. This chapter examines what measures might be possible.

The chapter first discusses key issues in HDIT quality assurance at the provider level and reviews existing standards for HDIT Next, it reviews past and present Federal quality assurance efforts in home care generally and in home infusion therapy specifically. Finally, the chapter examines the potential Federal role in assuring the quality of HDIT services provided to Medicare beneficiaries.[1] In this last task, the chapter reviews and critiques some of the requirements that might have been imposed upon providers in the wake of the Medicare Catastrophic Coverage Act of 1988 (MCCA)[2] (which was repealed before proposed regulations could be made final). It also examines potential roles for Medicine peer review organizations (PROS).

Summary of Conclusions

- The complicated and invasive nature of HDIT, the limited knowledge about the safety and effectiveness of some therapies in the home setting, and the comparatively frail health status of some Medicare beneficiaries warrant rigorous Federal oversight of HDIT quality assurance at least at the outset of a Medicare benefit, if not on a continuing basis.
- The degree to which Medicare can rely on State licensure and certification as a means of assuring HDIT quality is extremely limited. State regulation of HDIT providers is still absent in most States and inconsistent among States where it does exist. Federal policy could help to focus and standardize State HDIT regulatory efforts.
- The most consistent measures of HDIT provider quality currently available are standards published by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the National League for Nursing's Community Health Accreditation Program (NLN/CHAP). However, accreditation through these channels can be costly to obtain, and many existing providers have not sought it. Thus, Medicare should rely on State agencies, acting under explicit and consistent guidelines, to determine initial and continuing compliance with any conditions of participation (COPS) that Medicare develops. This will undoubtedly mean that some providers will need to seek multiple certification (e.g., compliance with JCAHO standards for private insurer reimbursement, State licensure requirements for facility operation, and an additional set of COPS for Medicare reimbursement), which many will find burdensome. Eventually, JCAHO- and NLN/CHAP-accredited HDIT providers could be granted "deemed status" if accreditation standards were commensurate with Medicare's COPS.
- Individual case review at some level is critical to assuring safety, appropriateness, and consistency in HDIT PROS could conduct at least retrospective review of a random sample of HDIT cases. Prior authorization by PROS for 100 percent of HDIT claims would be administratively costly and may not be necessary. As an

[1] OTA defines "quality of health care" as the evaluation of the performance of health care providers according to the degree to which the process of care increases the probability of outcomes desired by patients and reduces the probability of undesired outcomes, given the state of medical knowledge. Which elements of patient outcomes predominate depends on the patient condition (363).

[2] Public Law 100-360.

alternative, prior authorization, performed by either PROS or fiscal intermediaries (FIs),[3] could be reserved for certain therapies or certain patients who are determined to be at increased risk.

- Physician involvement is key to safe and effective delivery of HDIT services. To ensure appropriate physician oversight in the event of a Medicare benefit, HCFA could develop specific requirements or incentives and could charge PROS with reviewing compliance at the case level.
- Although many patient care services may be performed under contract rather than directly by an HDIT provider, certain functions should remain the primary responsibility of the provider. These functions include: initial patient assessment; quality assurance; maintaining clinical records; periodic drug regimen review; coordinating all HDIT services; guaranteeing 24-hour a day, 7-day a week availability of emergency services; and serving as the initial point of contact for patients in the event of questions, concerns, requests for supplies, and any emergencies.
- Because many of these functions require the expertise of a professional nurse well-versed in HDIT practice, an HDIT provider should employ directly at least one registered nurse (RN) whose training and prior experience qualify him or her to assume these responsibilities. In addition, an HDIT provider should have a qualified pharmacist either on staff or hired on a consulting basis.
- In the event of an HDIT benefit, Federal policies could help both patients and providers protect themselves from adverse outcomes and potential legal consequences of those outcomes. For example, providers could be required to ensure that patients understood their responsibilities for HDIT and consented to them in writing. Providers could also be required to give patients a single telephone number they can call in the event of any complication or emergency and be assured an immediate personal response.

Quality Issues in HDIT

Only the provider can ensure that good quality HDIT is provided on a day-to-day basis for each individual patient. As discussed later, many external standards are aimed at ensuring that providers have internal procedures for addressing quality-of-care issues. This section discusses some of the areas where provider procedures for quality assurance are especially critical.

Patient Screening and Assessment

Appropriate patient screening is the first and most important step in HDIT quality assurance the provider takes. For Medicare beneficiaries, who are more likely than other individuals to have fragile health conditions and limited functional capacity, careful assessment is crucial. As discussed in chapter 3, screening requires a thorough assessment of medical and nonmedical characteristics that render a patient appropriate or inappropriate for HDIT. These characteristics include stability of the patient's medical condition, willingness of the patient to undergo home therapy, knowledge and ability of patient (or caregiver) to perform self-care, equipment used, type and toxicity of drug, and environmental characteristics of the home setting (25).

But a thorough initial assessment also requires that the provider consider what types of services it is capable of delivering in a safe and efficient manner. If a patient requires services that a provider cannot deliver directly, the provider must either refer the patient elsewhere or make contractual arrangements to provide those services. The complicated nature of HDIT and the variety of factors that can influence ultimate patient outcome demand that patient screening be a multidisciplinary effort involving physicians, nurses, pharmacists, and other health professionals as necessary (e.g., a social worker) (131,270).

Patient and Family Caregiver[4] Training

Home care in general poses challenges for quality assurance because many patient care factors are not under the direct control of the provider. Procedures as critical as catheter flushing and intravenous (IV)

3 Medicare fiscal intermediaries include Part B carriers and Part A intermediaries who contract with the Health Care Financing Administration to process claims and perform other administrative tasks associated with the Medicare program.

4 "Family caregiver" refers hereto a family member or friend who assists the patient in self-care responsibilities on an unpaid basis. It does not include paid caregivers such as home health aides, for whose actions the employing agency is legally responsible.

drug administration are often performed by the patient without any supervision. A broad range of factors can affect the degree to which a patient is able or willing to comply with self-care instructions (table 5-l).

Providers exercise control over the quality of self-care techniques through comprehensive training of the patient and family caregiver. These techniques are not trivial to learn. In a recent survey, 92 percent of primary care physicians felt that patients and family members could be taught general self-care, but only 47 percent felt their patients could be taught the complex level of self-care required for HDIT (342). Medicare beneficiaries with fictional or cognitive limitations may find it especially difficult to perform certain procedures safely (134). In these cases, additional skilled nursing services may be necessary to ensure good-quality care (134) (see ch. 3).

Providers can undertake some specific measures to assure the quality of patient education. These include:

- *The use of standardized teaching and reference materials (210,296).* Patient instruction manuals should be written on a level that patients can understand (90,240,296).
- *Continuity in training with equipment and supplies. If* a patient is trained on one infusion pump and sent home with another, for example, he or she might not know how to start or stop the pump (390).
- *Continuity among instructors in patient instruction (e.g., dressing* changes and aseptic technique). Teaching different ways of undertaking self-care techniques can cause confusion, leading to poor performance of self-care tasks (210).
- *Beginning patient training before hospital discharge* (for patients whose therapy is initiated in the hospital) (240,296,364). Ideally, to ensure that the patient can transfer what he or she has learned to the home setting, a nurse or pharmacist would visit the home to observe that patient or family caregiver administer the frost home dose (240,364).

Patient Rights and Responsibilities

Existing standards for HDIT providers all require that the primary provider assume legal responsibility for the quality of any services provided to its patients on a contractual basis. They also require that the provider have written policies describing what specific services it is capable of providing and under what types of arrangements it provides them (178, 230,237). Most standards require nurses or other health personnel to document that patient training in self-care techniques has been completed satisfactorily (42,178,237).

The nurse's documentation does not itself constitute a patient's assertion of shared risk-i.e., that the patient understands his or her responsibility for self-care to reduce the risk of adverse health events. To effect such an assertion, the HDITprovider could

Table 5-l-Factors Affecting Compliance in Home Intravenous (IV) Antibiotic Therapy Patients

Physiologlcal factors
Age
Physical disabilities
Arthritis
Paralysis
Amputation
Decreased or poor vision
Cast requiring crutches, walker, or wheelchair
Neuromuscular dysfunction, multiple sclerosis, Parkinson's disease
Neuropathy secondary to diabetes mellitus
Diagnosis: duration and severity of disease
Dosing frequency and length of therapy
Pain
Lack of fine motor skills
Decreased strength and dexterity
Side effects of medications
Poor venous access requiring central line placement
Psychosocial factors
Education
Lack of care partner
Desire to go home
External locus of control
Socioeconomic status
Home environment
Community resources
Storage/refrigeration space
Fear/isolation
Decreased socialization (especially with multiple IV antibiotics and frequent dosing)
Cost/Insurance coverage
Sleep deprivation from frequent dosing
Other family responsibilities (e.g., mother with small children, ill spouse or parent, work, school)
Altered body image due to heparin lock/central line
Denial of diagnosis requiring IV antibiotic therapy
Inaccessible floor plan in home
Nursing/rnaditxl support
***Lack* of adequate patient education program**
Unclear understanding of rationale of therapy
Inaccessibility to nursing personnel on a 24-hour basis
Poor home followup by home care agency

SOURCE: Adapted from M.S. Neiderpruem, "Factors Affecting Compliance in the Home IV Antibiotic Therapy Client," *Journal of /intravenous Nursing* 12(3):136-142, May/June 1989.

be required to detail in writing those aspects of care for which the patient is responsible and have the patient acknowledge that responsibility by reading and signing an agreement.

Cost to the patient has been cited as a factor that can affect patient compliance in HDIT (240) (see table 5-l). To minimize patient concern about unexpected costs associated with therapy, providers could be required to inform patients before therapy starts about which specific items and services are covered, which are not, and what the patient's cost share will be.

Clinical Considerations

One of the greatest risks of infusion therapy is risk of secondary infection. Strategies for minimizing this risk in the home include:

- careful aseptic preparation of drugs and fluids to be infused;
- using the aseptic technique (see ch. 3, box 3-A) each time the line is accessed or the catheter exit site is exposed (e.g., during drug administration, dressing changes, catheter care);
- minimizing the number of times the patient's catheter, the administration set, or the container of infusate are exposed or changed (since each exposure increases the potential for contamination);
- periodically replacing devices or parts of the equipment that are subject to contamination (e.g., peripheral catheters, administration sets, falters, injection caps); and
- utilizing in-line antimicrobial filters (unless their use is contraindicated-see ch. 3) to eliminate possible contaminants from the infusate before it enters the vascular system.

To ensure that all these steps are followed, all patients, family caregivers, and patient care staff must be instructed in and be able to demonstrate the requisite techniques and precautionary measures.

Although patients may be expected to perform routine tasks associated with their therapy, they must have access to emergency assistance should any complications arise. The invasive nature and potential risks of HDIT demand that emergency services be available on a 24-hour a day, 7-day a week basis (174,178,230,240,248). This means that infusion provider staff (e.g., nurses and pharmacists) and the patient's physician must always be within reach by phone and able, if necessary, to see the patient personally or deliver emergency supplies immediately. To avoid patient confusion, providers may give the patient a single number to call in order to report any kind of emergency or problem. The staff person who answers that call can then immediately contact the appropriate staff, contract employees, or, if necessary, the physician, to respond to the situation.

Staff Qualifications

Regardless of how well organized and coordinated the services of an HDIT provider are, the quality of patient care will suffer if the individual staff members who provide those services are not adequately qualified to do so. HDIT involves a variety of skilled techniques with which the average nurse and pharmacist are not likely to be familiar (see table 5-2).

As discussed in chapter 3, formal training and certification in certain areas of specialty practice may be reasonably good indicators of staff capability and experience, but they do not guarantee proficiency in any given skill area. For example, a certified advanced practice RN may have difficulty inserting traditional peripheral catheters, while a basic RN who has pursued special training may be proficient in a technique as advanced as PICC (peripherally inserted central catheter) line placement. State pharmacy regulations in some cases act as indirect controls over general pharmacist qualifications, but they rarely offer a direct mechanism for assessing specific proficiencies (63). The burden therefore falls upon the employer to determine staff proficiency through employment screens, educational requirements, and on-the-job training in specific techniques.

In addition to knowing certain requisite techniques, skilled staff must be receptive and adaptive to the constant stream of new technologies that quickly become state-of-the-art in HDIT Recent technological advancements in home care have led home health agencies HHAs) and other home care providers to seek more highly skilled staff and to offer more in-service training in the use of new techniques and equipment (12,182). A 1987 study of 287 HHAs, for example, found that venipuncture, physical assessment, patient teaching, and IV therapy management skills were among the most highly ranked qualifications sought in agency nursing staff

Table 5-2—Examples of Home Infusion Nurse and Pharmacist Skills[a]

Nurse skills
• Traditional peripheral catheter insertion
• Peripherally inserted central catheter ("PICC line") placement
• Catheter maintenance and repair
• Familiarity with equipment and supplies used in drug administration
• Awareness of potential side effects of specific therapeutic regimens
• Ability to recognize and treat infusion therapy-related complications
• Ability to practice autonomously
• Patient training
• Ability to communicate effectively with the patient, pharmacist, and other staff
• Ability to assess infusion-associated emergencies and undertake appropriate steps
Pharmacist skills
• Compounding drugs for infusion
. Thorough knowledge of infusion drug stability and compatibility
• Thorough knowledge of potential infusion drug side effects
. Knowledge of therapeutic alternatives in the event of complications
. Familiarity with equipment and supplies used in drug administration
• Ability to communicate effectively with physicians, nurses, and other staff
. Ability to communicate effectively with patients directly
. Ability to assess infusion-associated emergencies and undertake appropriate steps

[a]Skills typically associated with home infusion therapy provision. Not all home infusion nurses and pharmacists need to be proficient in all skills listed. Larger home infusion providers maydivideresponsibilities between staff who specialize in one or more skill.

SOURCE: Office of Technology Assessment, 1992.

(182). Similarly, pharmacists must be up to date on newly emerging home therapies in order to advise physicians, nurses, and patients of therapeutic risks and alternatives.

The HDIT provider can help to maintain the proficiency of its staff by encouraging, mandating, and even providing ongoing education in new therapies, technologies, and techniques. The Federal Government can help ensure staff quality by requiring providers to offeror facilitate staff access to such training and by requiring that providers evaluate and document staff proficiency on a regular basis. A precedent under Medicare is the requirement that certified HHAs provide in-service education and competency evaluations for home health aides (SSA sec. 1891(a)(3)). Regulations issued by HCFA specify requirements for the curricular content of home health aide training programs (54 F.R. 155).

The Role of the Physician

The referring physician is the critical gatekeeper in HDIT. It is the physician who is responsible for prescribing the therapy, ordering all services provided to a patient, and consulting with HDIT staff in the event of any complications (121,178,237). The patient's physician must also be readily available for both emergency and routine consultation (e.g., to discuss lab results or changes to the therapy).

Because the physician bears responsibility for the plan of care, safe and effective delivery of HDIT services by the provider depends on the physician's understanding of the services and willingness to participate in care. However, the Office of Technology Assessment's (OTA's) discussions with physicians and HDIT providers suggest that physicians vary in their understanding of HDIT services and their willingness to play an active role in patient monitoring. Ideally, physician abilities should include home health care patient assessment skills; knowledge of home care therapies and technologies; knowledge of when to recommend specific nonphysician home health services; ability to play an active and effective role in home health care; and ability to evaluate the efficacy of home health care services and contribute to home health care quality assurance efforts (12).

Legal, financial, and professional concerns can impede physician involvement in home care (12). Physicians cite fear of malpractice, lack of compensation, and lack of faith in the quality and supervision of home care personnel as deterrents to referring their patients to home care (203,342). To date, legal concerns of physicians regarding home care have been largely theoretical, since few if any legal actions have been taken by home patients (12). Because HDIT services are generally delivered by licensed nonphysician health professionals who, along with their employers, assume legal liability for the care they provide, a physician's legal risks from referring a patient to HDIT may be no greater than those associated with referral to an acute-care hospital (248). However, the potential for physician liability-particularly where high-technology home care is involved-continues to be of concern, particularly where the physician feels he or she has little control over the conduct of the patient care received in the home (12,108,248). In a recent national survey of 1,100 primary care physicians,

over 60 percent felt there were significant differences in quality of care offered by different HDIT providers (342). Sixty-four percent of the physicians surveyed preferred providers who could offer both HDIT and general, comprehensive home health care services (342).

In the event of an HDIT benefit under Medicare, several strategies would be available to encourage adequate physician involvement in HDIT. For example:

- Regulations could require a minimum frequency of physician-patient and physician-provider contact. The appropriate frequency would probably vary depending on the type of therapy and the patient's overall medical condition.
- Medicare could provide financial reimbursement for the time physicians spend monitoring their HDIT patients (see ch. 7).
- Physicians could be involved in the development and periodic review of providers' intro-d quality assurance programs. This activity might increase physicians' sense of control over the quality of home services they prescribe for their patients.

Service Coordination

The decentralized nature of HDIT services poses an additional challenge for quality assurance. OTA's discussions with HDIT providers and patients strongly suggest that communication between the patient, referring physician, all HDIT staff, and any other parties either directly or indirectly involved in the patient's care are key to goodquality care and favorable outcome of therapy. Communication and coordination may be of particular concern to providers who subcontract pharmacy or nursing services.

Furthermore, some elderly patients require home care services beyond those generally required by younger, healthier patients on HDIT (e.g., home health aide services) (see ch. 3). Coordinating HDIT with general home health services (e.g., making sure home health aide staff are aware of the patient's HDIT regimen) can improve quality of care, reduce confusion for the patient, and cut overall costs of care by eliminating unnecessary duplication of services.

Many existing specialized HDIT providers have limited experience with elderly patients who require additional home services (see ch. 4). Of the various types of HDIT providers, Medicare-certified HHAs are probably the most likely to have had experience in coordinating these services because they provide the full range of Medicare-covered home care. Under anew Medicare benefit, Federal policy could address these issues by establishing explicit requirements for coordination of services between all agencies or individuals involved in patient care.

Existing Standards for HDIT Providers

Standards Issued by National Organizations

Standards developed by national organizations often serve as models for Medicare provider requirements. Existing published standards for HDIT providers or services, which vary in scope and detail, address areas such as:

- protocols and procedures for patient assessment and care,
- equipment and facility standards,
- staffing requirements and qualifications,
- the physician's role, and
- internal quality assurance program requirements.

Some of these standards are issued as guidelines for voluntary accreditation; others, for purposes of general reference and guidance. The two organizations currently offering accreditation for HDIT providers are JCAHO and NLN/CHAP (237). Other organizations that have issued advisory or model standards applicable to HDIT include the National Alliance for Infusion Therapy (NAIT)[5] (230), the Intravenous Nurses Society (INS) (174), and the National Association of Boards of Pharmacy (231). Most of these standards have been developed during the past few years and have undergone frequent revisions.

Although an increasing number of HDIT providers are obtaining accreditation, others have not pursued it. As of September 1991, JCAHO had accredited approximately 920 home infusion providers, including freestanding infusion companies, hospital-based providers, and visiting nurses associations that provide HDIT under contract (33). NLN/CHAP, which began offering accreditation for

5 Formerly the Alliance for Medical Nutrition.

HDIT in late 1989, had accredited a total of 38 providers as of November 1991 (95).

It is impossible to determine the actual proportion of existing home infusion providers that are accredited because of differences in the way providers are counted. Depending on the organization of a multisite provider and the way in which it seeks accreditation, JCAHO and NLN may accredit the parent organization as a whole or each individual branch or franchise separately (95). Furthermore, because both NLN and JCAHO have a 3-year accreditation cycle, some providers accredited only for noninfusion-related home health care may have begun to offer infusion therapy services in the interim. These providers, although accredited, are not accredited specifically for HDIT.

Standards Issued by Health Insurers

Some private third-party payers that cover HDIT services have developed specific standards or guidelines for providers that wish to obtain reimbursement. The purpose of these guidelines is both to assure quality and to contain costs.

Blue Cross and Blue Shield of the National Capital Area (BCBS/NCA), for example, has issued participation guidelines for home health care providers that specifically address HDIT services delivery (see box 5-A). Although the BCBS/NCA guidelines do not specify core staffing requirements, they do require that a single provider assume responsibility for the provision of all services. They also require that the primary provider hire, on at least a consulting basis, a licensed pharmacist proficient in infusion therapy practice. Under the guidelines, HDIT providers must have written policies and procedures regarding frequency of physician and staff contact, patient selection criteria, and monitoring requirements for each type of therapy they provide. Providers who deliver infusion antineoplastic therapy and total parenteral nutrition services must meet some additional requirements (42).

While many standard-both national standards and those issued by health insurers-require providers to implement an ongoing internal quality assurance program (178,230,237), few offer specific guidelines for structuring such a program. BCBS/NCA is an exception (see box 5-A) (42).

Developing Quality Indicators for HDIT Providers

Most HDIT providers operating today have some form of internal quality assurance program, although the degree of effort varies considerably (364). Most providers focus on structural and process measures of quality (see box 5-B). These include such measures as reading and recording of patient vital signs during each nursing visit, completion of required continuing education by provider staff, and documentation of patient training activities.

Although structure and process measures can provide a strong quality assurance framework for the operations of an HDIT provider, specific quality of care problems may go unnoticed if patient outcome criteria are not also examined regularly (96). Potential criteria that can be examined in an ongoing internal quality assurance program are as numerous as the provider's list of written protocols for patient care. If performance of every protocol is documented in the patient records, then those records can be examined for compliance in every aspect of patient care. Depending on the number of patients served by a provider, review can be performed on all or on a sample of patient records. Specific outcome criteria that might be helpful to monitor include:

- rate of equipment malfunction (103);
- rate of nonroutine infusion restarts and reasons for these restarts (81);
- level of patient satisfaction with HDIT services and specific reasons for dissatisfaction (this could be accomplished through periodic retrospective patient satisfaction questionnaires) (219);
- specific patient complaints (e.g., request for a different professional caregiver) (219);
- rate of infusion therapy-related complications (e.g., phlebitis, infection, catheter occlusion, air embolism, infiltration) (96);
- rate of early detection and treatment of drug side effects (e.g., laboratory testing performed and results reported according to protocols, appropriate followup by physicians and nurses) (96); and
- effectiveness of HDIT (therapeutic goals achieved; no recurrence of condition noted 6 months after last treatment) (96).

Studying outcomes of HDIT is useful not only for the identification of noncompliance with specific

Box 5-A—Blue Cross and Blue Shield of the National Capital Area Standards for Participating Home Care Providers

Blue Cross and Blue Shield of the National Capital Area has published standards for home infusion providers who wish to obtain reimbursement from the plan. These standards address areas such as:

. licensure, organization, governance, and management;
development of written policies and procedures for all treatment modalities;
• monitoring frequency of physician contact;
. professional training and continuing education for nurses and pharmacists;
coordination of services;
• 24-hour availability of services;
. testing and maintenance of equipment;
* patient assessment and training;
• arrangements for collection, analysis, and reporting of laboratory test results; and
. availability of social work services to patients as needed.

In addition, the standards set the following specifications for an ongoing internal quality assurance program:

1. There is evidence of an ongoing quality assurance program supported by the provider to monitor the quality and appropriateness of patient care and services provided. The program includes, but is not limited to:
   assessment of the competency of personnel providing services, including the appropriateness of responsibilities assigned to each individual;
   . appropriate execution of physician orders;
   * effective emergency response to patient or caregiver problems;
   • evaluation of services including review of provider policies and procedures;
   * ongoing, concurrent review of any infections, complications, adverse reactions, and therapeutic failures;
   * review of the records of maintenance, repairs, and faulty supplies for all equipment;
   * evaluation of the effectiveness of the patient and caregiver training and education program; and
   • hiring a fully licensed pharmacist as a consultant to the staff of the infusion therapy program to participate in the development of educational programs, policies and procedures, and ongoing quality assurance activities.
2. Assessment of documentation within the medical record includes, but is not limited to:
   designation of the attending physician primarily responsible for the patient's therapy at home;
   * initial and ongoing physical and psychosocial assessments;
   • evidence that the patient and/or caregiver has completed training;
   presence of a plan of treatment;
   signed and dated progress notes for each home visit and telephone contact noting: treatment administration, response to therapy, complications or adverse reactions, modification in prescription, patient/caregiver compliance, condition of infusion site, and catheter site changes.
   appropriate and complete diagnostic and therapeutic orders signed by the attending physician;
   • relevant laboratory test determinations and procedure findings;
   * pharmacy dispensing record including date and time; solution type, volume, and lot number, medication additives; and dose and infusion rate;
   documentation of ongoing contact with the attending physician and other agencies/vendors providing patient services;
   • supplies and equipment used; and
   a summary statement at termination of therapy which includes results of therapy, complications, outcomes, and disposition or status of the patient upon discharge from care.

SOURCE: Blue Cross and Blue Shield of the National Capital Area, ' 'Guidelines for Participation of Home Care Providers," Washington, DC, February 1989.

protocols, but also for gaining a general base of knowledge about the problems associated with HDIT and how to resolve them. As HDIT evolves, careful documentation of patient problems and outcomes will be crucial to the development of rational coverage and delivery policies. Some providers have already begun to incorporate specific outcome measures into their quality assurance programs. NLN/CHAP accreditation surveys for home infusion providers also incorporate outcome

Box 5-B-Quality Assurance in Home Care

Quality assessment is the measurement and evaluation of the quality of health care provided to individuals or to groups of patients. ***Quality assurance*** is the conduct of activities that safeguard or improve the quality of health care by correcting deficiencies found through quality assessment (363).

Quality assessment involves the application of structural, process, and outcome measures (98). Structural measures assess whether the availability and organization of resources (e.g., quality of personnel, equipment, facilities, and coordination of services) are adequate to assure a certain standard of quality. Process measures examine the amount of careprovided and the performance of health professionals who deliver it by comparing actual care delivered with accepted standards. Outcome measures assess the relative effectiveness of structure and process in determining quality of care by looking at specific patient outcomes (e.g., health status, incidence of complications, satisfaction with care). While structural and process standards can measure the ***capacity*** to deliver quality care, only outcome measures can determine whether providers are in fact meeting that capacity (292,293).

Quality assessment and assurance methods for ambulatory and home care are less developed than those for inpatient care (48,192,252,253,292,395). Quality assurance efforts in home care to date have focused on structural and process measures rather than patient outcomes, which are less well-researched and designed. State licensure, accreditation, and Medicare certification are the three primary quality assurance mechanisms used in home health care today (292).

However, sophisticated and more narrowly defined home services such as infusion therapy may be conducive to outcomes assessment in a way that other home health services are not. For example, IV antibiotic therapy outcome can be measured by resolution of the infection within a given time period and by nonrecurrence of that infection for a specific time period following completion of therapy. In contrast, "outcomes" of ongoing home health services for a chronic arthritis patient are less tangible.

Even the most sophisticated and comprehensive quality assurance program cannot guarantee successful patient outcomes, because factors other than quality of care can affect these outcomes (25,47,293). This maybe particularly true in the home setting where many of the factors that can affect patient outcomes are beyond the provider' control (25). Thus, screening patients for some of these potentially problematic factors (e.g., ability to perform self-care tasks adequately) becomes key in HDIT quality assurance.

and consumer-oriented measures of quality (237), and JCAHO has put together a task force to examine outcome-oriented quality indicators for HDIT (229).

State Regulation

Medicare sometimes looks to State regulatory mechanisms as one means of assuring the level and quality of services offered by participating providers. Generally, if a State has applicable licensure or certification laws, Medicare requires that a provider—whether it be a physician, a hospital, or an HHA-be licensed or certified according to those laws in order to qualify for reimbursement from the program (74).[6]

The extent to which State licensure and certification laws can serve as reliable and consistent measures of quality for nonhospital health care settings, however, is limited (352). The requirements set forth by States vary considerably in depth and scope, and some States have no regulations at all for certain types of providers (e.g., HHAs and hospices) (352). As of March 1991, for example, 11 States still had no licensure requirements for Medicare-certified HHAs, and 20 States had no licensure requirements for non-Medicare-certified HHAs (233).[7]

To the extent that HHAs are involved in any aspect of HDIT, Medicare regulation and existing State regulation of HHAs could serve as an indirect means of assuring the quality of those HDIT services. At present, however, Federal regulation of Medicare-certified HHAs does not directly address quality assurance issues unique to HDIT or other high-technology home services (352). The extent to

[6] *The same rule was* to apply under the proposed regulations for home IV drug therapy providers issued pursuant to the MCCA (54 F.R. 172—see appendix C).

[7] Medicare began covering services provided by HHAs that met its conditions of participation in 1966. Initially, private HHAs were allowed to participate in the Medicare program only if they were licensed pursuant to State law (74). In 1981, requirements were relaxed to allow for the participation of private agencies in States with no licensing mechanism (74).

which State HHA regulations specifically address HDIT services is unknown, but since many States have used Medicare COPS as a model for their own HHA regulations (232,233,292,352), it may be presumed that it is very limited. For new services such as HDIT, it may be years before States develop specific licensure or certification mechanisms, if they develop them at all.

Most of the existing State regulations for HDIT providers have been developed and implemented by State boards of pharmacy. A May 1989 survey of all 50 State boards of pharmacy found that 15 States had published some relevant regulations and an additional 18 States were planning to do so (210). The scope of these regulations varies considerably from State to State, however. Some apply only to preparation of parenteral drugs, while other States define and regulate a broader role for pharmacies in HDIT provision:

- At least two States require separate licensure for home infusion therapy pharmacy providers (366). Regulations in Washington State address the full scope of home infusion therapy services, including nursing, pharmacy, delivery, coordination, and physician involvement. Washington has even designed and implemented special training programs for inspectors of home infusion pharmacies/providers (210). Regulations in New Jersey are more limited in scope (295).
- An additional 20 States claim to have some form of home infusion therapy regulations in place, but OTA found that most of these regulations address only the preparation and labeling of parenteral solutions rather than the broader range of home infusion therapy services (366). Regulations typically address areas such as physical plant, staffing, procedures, internal quality assurance, and recordkeeping (63,366). Most States have specific regulations for the handling and preparation of cytotoxic drugs (e.g., antineoplalstic drugs) (63,366). Regulations vary, however, in their description of the scope of pharmacist responsibilities for patient care (63).
- As many as 28 States claim they do not currently regulate home infusion pharmacies. Of these, eight claim that such regulations are currently under development (210,366). However, some of these States may actually regulate parenteral drug preparation at a level commensurate with that of States that claimed they do regulate home infusion pharmacy (366).

The Federal Role in HDIT Quality Assurance

The high level of coordination and skill involved in the provision of HDIT services raises concerns that, under Medicare, all providers might not offer a consistent acceptable level of quality services. Under a separate HDIT benefit, Medicare could exercise control over the quality of HDIT services by:

1. establishing COPS for providers, implementing survey and certification procedures to ensure compliance with those COPS, and applying penalties for noncompliance;
2. conducting case-by-case review (both prior and retrospective), either through FIs or PROS;
3. developing a list of covered drugs that are generally safe and appropriate for home delivery; and
4. creating a system of payment that provides appropriate incentives for the referral of patients to HDIT and for the participation of qualified health professionals (nurses, pharmacists, and physicians) in the conduct of that care.

The following section focuses on the first two mechanisms. Coverage and payment considerations are discussed in chapters 6 and 7 of this report, respectively.

Current Medicare Quality Assurance Efforts Relevant to HDIT

Under Medicare, all qualifying providers[8] must comply with certain conditions set forth by the Secretary of the Department of Health and Human Services in order to obtain reimbursement for their services (42 CFR 417). These conditions are Medicare's most systematic method of assuring quality of care at the provider level.

Existing Medicare coverage for HDIT is limited and fragmented. The key sources of coverage are the

[8] "Providers" under Medicare are defined to include the following: hospitals, skilled nursing facilities, comprehensive Outpatient rehabilitation facilities, home health agencies, hospices, and providers of outpatient physical therapy or speech pathology services (42 CFR 417,416).

Part A home health care benefit and the Part B durable medical equipment (DME) benefit (see ch. 6). Existing COPS for HHAs are broad and do not address many of the quality assurance concerns specific to HDIT. DME suppliers, because they are suppliers of equipment rather than providers of services, are not subject to any direct Medicare quality control measures in spite of the fact that they are another major source of Medicare-covered HDIT.[9]

Under Part A, certified HHAs are required to comply with specific COPS that include staff qualifications and annual program evaluation by a group composed of HHA staff and consumers (42 CFR 484). These COPS, discussed in more detail later in this chapter, are for home health services generally and do not specifically address HDIT quality concerns. Medicare PRO oversight of home health services, also discussed later in the chapter, has been limited and indirect.

Drugs and other fluids administered via an infusion pump are occasionally covered under the Part B DME benefit along with the pump (see ch. 6) (365). Direct Medicare quality assurance efforts are virtually nonexistent, however, because DME suppliers who bill Medicare are not subject to any specific COPS or conditions of coverage (74). They are required by law to provide instruction in the operation of DME, but the degree to which they do so is currently not documented or regulated, and in some cases it may consist merely of including written manufacturers' instructions in an equipment delivery (156).

The Safe Medical Devices Act of 1990 requires that device user facilities[10] report medical device malfunction events that contributed to the death or serious illness or injury of a patient to either the manufacturer or the Secretary of the Department of Health and Human Services within 10 days of their occurrence (Public Law 101-629).[11] Such reports could be useful for identifying and monitoring the use of potentially harmful HDIT devices (e.g., an infusion pump prone to malfunction).

Because current Medicare coverage for the components of HDIT is very fragmented, a comprehensive HDIT quality assurance program is not possible at present. The responsibility for quality assurance is therefore implicitly relegated to the prescribing physician, who often has little control over the services provided to HDIT patients. Some carriers (the Part B FIs) have been reluctant to cover drugs under the DME benefit because they perceive the lack of a defined 'infusion provider' '—and the qualifications that such a designation might require-as a quality problem (365). Some carriers go so far as to require preauthorization of all claims involving payment for drugs under the DME benefit (365).

Proposed Requirements Under the MCCA

If a Medicare HDIT benefit were created, COPS would probably need to be established specifically for providers of this service. Fortunately, HCFA has already given considerable thought to developing COPS for HDIT providers, because the now-repealed MCCA was to have included home IV drug therapy .12 Proposed regulations issued pursuant to the MCCA specified detailed COPS for qualified providers (see app. C). The proposed COPS addressed:

- compliance with Federal, State, and local laws,
- governing body and administration,
- patient selection,
- plan of care and physician review,
- maintenance and handling of central clinical records,
- core staff and services,
- nursing services,
- pharmacy services,
- patient and family caregiver evaluation and instructions,
- written protocols and policies,
- provider quality assurance activities, and
- infection control (54 F.R. 172).

9 Medicare also covers total parenteral nutrition, another form of home infusion therapy, under the Part B prosthetic devices benefit (see ch. 6). Coverage is limited to nutrients, equipment, and supplies. Medicare has no structural quality assurance requirements for total parented nutrition (TPN) providers.

10 Device user facilities include hospitals, ambulatory surgical facilities, nursing homes, or outpatient treatment facilities that are not physicians offices (e.g., HHAs, DME suppliers) (Public Law 101-629).

11 Reporting provisions of the Safe Medical Devices Act of 1990 were effective as of Nov. 29, 1991.

12 To develop the COPs, HCFA sought guidance from industry representatives, health professionals, professional associations, organizations that currently accredit or publish standards for home IV drug therapy providers, and other knowledgeable parties (54 F.R. 172).

Although the proposed rules were never made final, they generated mostly positive comments from responding organizations (167). The remainder of this section focuses on specific areas of the proposed COPS that deserve additional attention if a new benefit were to be implemented.

Routes of Drug Administration

The MCCA benefit was to cover IV therapy alone. If Congress were to develop an HDIT benefit that also covered other routes of administration (e.g., subcutaneous, intraspinal), relevant COPS and other regulations would need to address the attendant differences in intensity of services, required equipment and supplies, and specific techniques used. For example, the proposed conditions issued pursuant to the MCCA required that peripheral catheters be changed at least every 3 days (54 F.R. 172). Although existing standards support the 3-day rotation of peripheral *venous* catheters, peripheral arterial catheters are generally changed less frequently, and subcutaneous infusion needles are changed every 48 hours (see ch. 3) (174).

Patient Care Policies and Physician Review

The proposed regulations specified that it would be the referring physician's responsibility to initially determine whether home IV therapy is appropriate for the patient and to prescribe the drug regimen for that patient. In addition, they required the referring physician to review the plan of care at least every 30 days (54 F.R. 172).

The proposed rules made no specific requirements for frequency of contact between patient and physician during the course of therapy, however. For a substantial proportion of HDIT patients, a 30-day minimum review requirement might mean that their plan of care would undergo only initial review, leaving the possibility that some complications or side effects of therapy would go unnoticed. More frequent physician contact during therapy may be especially appropriate for elderly patients with multiple health problems. Specific requirements for patient-physician or provider-physician contact could even be established by type of therapy or type of condition. For example, some programs recommend weekly physician visits for patients on antibiotic therapy (91). In addition, HCFA could require more frequent comprehensive review of the plan of care by the referring physician.

Patient Selection

The proposed rule required that a provider screen each patient before acceptance, and that this screening be performed by a multidisciplinary team of experts in home IV therapy. Both medical criteria (e.g., the patient's clinical status) and nonmedical criteria (e.g., patient's ability to undertake self-care) were to be considered in patient selection (54 F.R. 172).

The proposed conditions did not provide specific screening criteria to use in determiningg that patients "have a clinical status that allows IV drugs to be safely administered at home. " Although it is ultimately the physician's responsibility to determine whether a patient's medical condition is sufficiently stable for HDIT, additional requirements might aid providers or other parties involved in initial determination of appropriateness of HDIT (e.g., PROS or FIs). As discussed below, the MCCA mandated PROS to perform prior authorization on all home IV therapy claims. Presumably, each PRO would develop its own screening criteria to determine safety and appropriateness. Separate criteria in each PRO jurisdiction, however, could lead to inconsistency in coverage and quality of care.

In addition, if a new Medicare benefit were to cover HDIT for patients not capable of self-care, more explicit patient selection and provider services requirements would need to be developed.

Staffing and Services

The Health Care Financing Administration(HCFA) proposed that home IV therapy providers meet certain staffing and service requirements. Specifically, the proposed regulations stated that:

- Home IV providers must directly employ at least one full-time-equivalent (FTE) nurse or pharmacist.
- The home IV provider must perform the following services directly:
  - -developing, supervising, and coordinating all nursing and pharmacy services;
  - —assuring that only qualified personnel provide home IV services;
  - -consulting with pharmacists involved in patient care to coordinate the plan of care with the physician; and
  - —performing quality assessment activities including drug regimen review.

There was extensive debate both before and after publication of the proposed rule regarding core staffing requirements (167) (52 F.R. 172). The rationale behind the proposed requirement for either a full-time nurse or a full-time pharmacist was that HDIT involves both nursing and pharmacy services, and that a provider should therefore have at least one of either of these professionals within its direct employ. A nurse or a pharmacist alone, however, would not have been able to provide all of the proposed core services. For example, a nurse would not be capable of drug regimen review, and a pharmacist would not be capable of developing and supervising nursing services. HCFA had initially considered requiring that *both* a nurse and a pharmacist be employed directly, but professional provider organizations objected on the grounds that this would disenfranchise many existing providers (e.g., HHAs with no in-house pharmacy) (54 F.R. 172) (167).

A possible solution to this problem would be to require that providers who have only an RN under direct employ maintain a consulting contract with a pharmacist who is experienced in HDIT. This pharmacist would assist the HDIT provider on an ongoing basis with development, coordination, and evaluation of pharmacy services and with periodic drug regimen review. (This model is similar to that used by BCBS/NCA (42)).

Nursing Service-The proposed rule required that ***all nurses*** providing home IV services be RNs who had at least 2 years' experience in patient assessment and infusion therapy. Nurses were required to be proficient in all procedures directly related to IV therapy and the insertion of all types of needles and catheters commercially available (52 F.R. 172).

The comprehensiveness of these proposed skill requirements may be unrealistic in the existing specialized HDIT market. HDIT providers—especially those with numerous staff-tend to divide patient care responsibilities among nursing staff according to individual nurses' skill levels (see ch. 3, box 3-C). For example, one nurse may specialize in PICC line placement, performing it on all of the providers' patients, while another may be responsible for placement, maintenance, and repair of standard peripheral catheters. Still other nurses may specialize in the care of patients with central access devices.

In addition, although some HDIT-related procedures are skilled procedures that *mu@ be* performed by an RN (e.g., venipuncture), other tasks (e.g., dressing changes and central catheter care) may be performed by other staff who have been trained properly and who work under the supervision of an RN. Some providers use licensed practical nurses to perform noninvasive catheter care and drug administration procedures (3).[13] Greater flexibility in staff skill requirements could improve the ability of providers to recruit qualified staff. For example, most home infusion provider nursing staff today are not proficient in inserting PICC lines, a type of "commercially available" catheter (see ch. 3). Although the level of proficiency and experience described in the proposed conditions is not reasonable to require of each *individual* nurse involved in HDIT, it is reasonable to require it of at least one nurse who is employed directly by the provider.

Pharmacy Services-HCFA did not address the qualifications pharmacists, despite the fact that home infusion pharmacy requires expertise and knowledge as specific as that in infusion nursing. In the future, specific experience in relevant aspects of HDIT phamacy (e.g., drug compounding, patient education, drug therapy monitoring, drug regimen review) could be required of pharmacists whose responsibilities included such activities.

HCFA's proposed standards for drug preparation were also inconsistent in some areas with existing private standards for home infusion pharmacies. For example, the proposed regulations would have allowed either clean work benches *or* laminar flow hoods for the preparation of IV drugs (54 F.R. 172). In contrast, JCAHO, NLN/CHAP, NAIT, and American Society of Hospital Pharmacists (ASHP) standards all require the use of laminar flow hoods to protect against microbial and particulate contamination (178,199,230,237).

Patient and Family Caregiver Assessment and Training

Proposed COPs required that an RN perform patient and family caregiver evaluation and educa-

13 HCFA's experience that "none of the entities [it] contacted allowed anyone but a registered nurse to furnish nursing services connected with IV drug therapy" (54 F.R. 172) may have been influenced by the fact that, at the time the proposed rule was published, it had contacted mostly proprietary home IV drug therapy providers (167).

tion. This requirement would have been problematic, for two reasons. First, patient and family caregiver evaluation is often a multidisciplinary effort that involves not only the nurse but the referring physician, pharmacist, and other health professionals such as a nutritionist or social worker. Second, some aspects of patient/family caregiver instruction (e.g., discussion of side effects of therapy, use of infusion devices, self-care techniques) may sometimes be appropriately given by pharmacists or other types of health personnel, such as specially trained pharmacy technicians (see box 3-C) (15). Future COPS for HDIT providers could reflect this practice by allowing a broader range of health professionals to perform some of these functions, perhaps under the supervision and coordination of a qualified RN. Also, any future COPs might want to specifically address patient responsibilities in HDIT.[14]

Protocols and Policies

First-Dose of Medication—Proposed COPS required that the first dose of any IV therapy be given under the direct supervision of a physician *or* nurse who is equipped with resuscitation medication and equipment to treat anaphylaxis (54 F.R. 172). Alternatively, under a new benefit, HCFA might require that the first dose of infused drugs with a known potential for allergic reaction or other complications always be delivered under a physician's supervision.

The nature of the supervision could vary depending on the setting in which the initial dose is given. For example, patients who are discharged to HDIT from the hospital could be required to receive their first dose in the hospital where physicians are readily available. For outpatient-initiated therapy, patients could be required to receive the first dose in a physician's office or hospital outpatient setting. For outpatients who are homebound, special exceptions could be made or, alternatively, a physician home visit could be required for the initial dose.

Catheter Care-Catheter care requirements in the proposed rule were generally consistent with recognized standards of infusion nursing practice (174,199,237). In light of the rapid pace of technological innovation and change in HDIT, however, rigid standards such as those proposed might have required frequent updating to stay abreast of current practice. For example:

- **The** proposed rule required that the sites of all peripheral catheters be rotated by a nurse at least every 3 days (54 F.R. 172). Some newer catheters can remain in place longer than 3 days (see ch. 3) (364). Alternatively, HCFA could require that the catheter site be inspected by a nurse at least every 3 days and changed as necessary.
- The proposed rule required that IV administration sets be changed at least every 24 hours (54 F.R. 172). Although support for this requirement may be found in existing standards or professional literature, the appropriate frequency of administration set change varies with the particular therapy and dosing fiquency. For example, patients on continuous infusion may only change their administration set every 5 to 7 days, while patients using disposable infusion devices may change their administration sets up to 4 times a day by default, because the administration set is integral to the device. A less rigid requirement for administration set change could thus be appropriate.

Air-Elimination Filter and Catheter Testing—As an additional measure of quality control, HCFA proposed that nurses routinely collect a random sample of discarded catheters and air-elimination falters and send them to a laboratory for analysis of particulate and microbial contamination (54 F.R. 172). Both ASHP and the Association for Practitioners in Infection Control objected to this condition on the grounds that the catheters and falters could easily become contaminated between the time they were removed from the patient and the time they were examined in the laboratory (1,199). Both these groups recommended culturing the catheter or filter only when there were clinical signs of possible infection (1,199).

Drug Therapy Review—The proposed rule required that the pharmacist review the prescribed combination of IV drugs and equipment for appropriateness before therapy began. In addition, the pharmacist was to be required to review the appropriateness of drug therapy at least every 3 days and

14 For example, the patient/family caregiver might be instructed and required to document on a chart each drug and solution administration or other HDIT-related procedure (e.g., catheter flushing, administration set change, dressing change) and note any attendant difficulties they experienced. These charts could be incorporated into the central clinical record to complement nurse and physician notes.

report significant findings to the physician (54 F.R. 172).

Review every 3 days may not be necessary in all cases, and it may sometimes be logistically difficult if the pharmacist must meet with the patient's nurse in order to review appropriateness. Some providers have most staff on site and can hold regular meetings (e.g., routine drug regimen review once a week) attended by all members of the provider staff. Providers who send staff to patients' homes and/or subcontract for pharmacy services, however, may have to resort to other modes of communication (e.g., telephone, facsimile, extensive patient encounter notes) to accomplish the conferencing necessary for ongoing drug regimen review. HCFA might instead require pharmacists to review appropriateness of therapy at least once a week and whenever requested to do so by patient care staff.

Patient Rights and Responsibilities-The proposed conditions specified that treatment should begin only if the provider is capable of furnishing care at the level of intensity required by the patient. In addition, providers were to inform patients of their responsibilities and rights in writing upon initiation of therapy. The proposed rule also required providers to establish procedures for patient complaints (54 F.R. 172).

Under anew benefit, HCFA might want to further require that written consent be obtained from patients before therapy begins. For instance, providers could be required to obtain signed statements from patients documenting that they fully understand and are able and willing to perform all aspects of required self-care, that they are aware of the risks associated with their therapy, and that they understand what their share of costs for the services are expected to be.

Provider Quality Assurance Activities

The proposed conditions required home IV providers to maintain ongoing, systematic quality assurance programs to evaluate the quality and appropriateness of patient care, correct deficiencies, and improve patient care (54 F.R. 172). A written evaluation plan was to include scope and objectives of quality assurance activities, specific activities to be monitored, methods for evaluation and reporting of results, mechanisms for corrective action, and staff responsibilities for each activity. Home IV providers were to be required to collect and analyze data *at least annuully* on the length of therapy by diagnosis and treatment; patient complications and rehospitalizations; and the nutritional status of patients. In addition, providers would have been required to determine that activities had been carried out appropriately (e.g., that delivery of drugs and equipment was timely, that any peripheral catheter patient had their catheter rotated by a nurse every 3 days, etc.) (54 F.R. 172).

The proposed quality assurance standards lacked specificity in some areas. For example, they failed to specify whether the quality assurance activities (e.g., collecting data on negative outcomes) should be applied to all cases or to a sample of cases. Also, although the proposed COPS required the provider to specify "staff responsibilities for each activity in the quality assurance program," they did not specify where activities should involve both nursing and pharmacy Staff.

Nor did the rule specify a role for the patient in the ongoing quality assurance program. Providers could have been required to conduct an exit interview with a sample of patients (or with all patients), for example, to verify that care documented in the clinical record was in fact performed.

Determining Provider Compliance With Conditions of Participation

Activities of State Survey Contractors

To determine compliance with its COPS, HCFA generally relies on a State agency (usually a department of health or department of aging) with whom it contracts to conduct periodic surveys of all facilities in the State (351). State surveyors are given guidelines and, in some cases, specific assessment tools, to use in the survey process for each type of facility.

Because the proposed COPS for home IV therapy providers were never implemented, mechanisms for determining provider compliance were never tested. However, past experiences with HHAs can shed light on potential problems in determiningg compliance with any future Medicare COPS for HDIT providers.

In order to qualify for reimbursement through the Medicare program, HHAs must comply with COPS that address the following two general areas:

- *administration* (acceptance of patients, plan of care, patient rights, medical supervision, disclosure of information, organization and administration of services, policy review), and
- *furnishing of services (staff* qualifications and *tr*aining, maintenance of clinical records, program evaluation, survey and certification process) (42 CFR 484).

Compliance for both initial and continuing certification is determined by surveyors[15] from a State agency who make an unannounced visit to the HHA at least once every 15 months. On each visit, a "standard survey' is conducted that assesses compliance with a specified subset of the COPS. The survey visit can include review of a random sample of medical records,[16] review of written patient care protocols, verification of staff qualifications and training, site visits to patients' homes t. witness the direct provision of care and interview patients regarding their satisfaction with the HHA services. Based on the standard survey, the surveyor makes a judgment as to whether the HHA seems to be providing standard or substandard care. If it is judged substandard, the State conducts an extended survey that assesses compliance with the exhaustive list of COPS. If the HHA fails the extended survey, sanctions can be applied.

The Omnibus Budget Reconciliation Act of 1987 (OBRA-87)[17] mandated that quality of care measures based on patient outcomes be incorporated into the HHA survey procedure. Measures such as death or readmission to a hospital or nursing home during or shortly after termination of treatment are among those to be used to detect problems (42 CFR 484). OBRA-87 also mandated that visits to the homes of HHA patients be included in the survey process to enable direct observation of care currently being provided, and to ensure that procedures documented in the patient record were actually performed (351). Accordingly, HCFA has published revised COPS for HHAs (42 CFR 484) and has issued instructions to State survey agencies on how to conduct outcomes-oriented surveys (370).

Because the outcomes-oriented survey and certification mandates did not go into effect until March 1991 (132), it is too early to know whether they are in fact improving the quality of HHA care. However, a 1989 study by the U.S. General Accounting Oftlce (GAO) found numerous problems with the conduct of HHA surveys by State agencies prior to implementation of the new provisions. These included:

- inadequate guidance and oversight by HCFA on conduct of surveys;
- inconsistent interpretation by State surveyors of requirements for compliance with Medicare COPS;
- inconsistency in scope of surveys and methods used to select samples of records for review;
- lack of coordination between State survey agencies, FIs, and Medicare PROs;[18] and
- lack of personnel training standards for high-technology services such as infusion therapy (351).

Although some of these problems have been addressed in the new instructions issued by HCFA (132), it remains to be seen whether they will be resolved.

If future HDIT coverage under Medicare entails a new class of certified providers, similar problems could arise. Problems might be avoided by improving the clarity of the conditions themselves, offering more thorough and consistent guidance to the State agencies that conduct the surveys, and mandating and facilitating cooperation between all organizations involved in HDIT quality of care review (e.g., PROS, FIs, and relevant State licensing agencies) (351).

Reliance on Standards Issued by National Accrediting Bodies

Section 1865 [a] of the Social Security Act permits HCFA to grant "deemed status' '-i.e., to consider certain health facilities as meeting any or all of Medicare's COPS for that type of facility-to facilities accredited by a national accreditation program (SSA, sees. 1864, 1865[a]). Deeming authority is monitored through a validation review process in which a small sample (5 percent) of providers are surveyed directly by HCFA to test how

15 HHA surveyors are always registered nurses.

16 Sample size depends on the size of the agency and is defined as a fixed number of records rather than a percentage (132).

17 Public Law 100-203.

18 PROs are required by law to coordinate their efforts with other reviewing bodies.

well the accrediting organization's standards continue to reflect Medicare's COPS (55 F.R. 51434).

Until last year, HCFA had extended deemed status only to hospitals accredited by JCAHO (127).[19] In October 1991, HCFA granted deemed status to HHAs accredited by NLN/CHAP. JCAHO has also applied to HCFA for recognition as a deeming authority for HHAs, but authority has not yet been granted.

It is unlikely that Medicare could initially rely on "deeming authority" as a mechanism for certification of HDIT providers due to inherent limitations of the standards themselves and the accreditation processes. First, accreditation surveys performed by national organizations may not be as good a measure of compliance with COPS as surveys by State agencies, because they tend to be conducted less frequently and are generally scheduled in advance, giving providers the forewarning they need to get "Up to speed." To date, JCAHO has conducted full surveys once every 3 years and has given providers a minimum of 4 weeks' formal notice (179).[20] NLN/CHAP also operates on a 3-year accreditation cycle, but it conducts abbreviated annual surveys in interim years and all of its site visits are unannounced (237).

Also, the cost of obtaining accreditation through JCAHO or NLN/CHAP may deter some smaller providers from seeking it. JCAHO's average fee for a single-site HDIT provider is approximately $4,800 for the full three-year accreditation period (33). The 1992 NLN/CHAP fee for a medium-sized single-site provider whose net revenue was under $1 million would be roughly $13,000 over a 3-year period (95).[21]

Case Review; Role Of Medicare Peer Review Organizations and Fiscal Intermediaries

While Medicare relies on State and national survey and certification processes to determine compliance with specific COPs, it generally relies on PROS to assess the quality and appropriateness of care at the individual case level. Mandated under the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248), PROS have the authority to deny Medicare payment for inappropriate or unnecessary services and to discipline and/or sanction providers and practitioners to correct any unacceptable medical practices (363).

Because HDIT is a complicated service to deliver, and an HDIT benefit might be prone to overutilization if Medicare did not cover other outpatient prescription drugs (see ch. 6), some level of PRO review of claims would be warranted. A minimal level of PRO review would be retrospective review of a random sample of claims within each PRO jurisdiction. (Even this form of review is currently not required for Medicare home health services claims.) The most rigorous level of review, which was to be required under the MCCA benefit until 1993, would be prior review and authorization of all HDIT claims.

Current PRO Activities

To date, PROS have been involved primarily in review of claims for hospital and physician services. Due to the large volume of Medicare claims, review is usually conducted retrospectively on a random sample of claims. However, prior review is currently required for a few select procedures. (See box 5-C for a description of PRO prior and retrospective review processes.) PROS also review cases where quality of care has been brought into question, but this mechanism is limited by the ability and willingness of beneficiaries, providers, and health professionals to recognize and report suspected deficiencies or problems.

Because the initial PRO claims review is usually performed by individuals (usually nurses) who are not experts in the particular type of care provided, a key element to the prior review process is explicit review criteria for the service in question (183). At present, Medicare instructs each PRO to develop its own criteria for care, diagnosis, and treatment based

19 Until 1984, allowance for "deemed status" was limited to hospitals, skilled nursing facilities, and HHAs. Legislation in 1984 (Public Law 98-369) expanded the allowance to include rural health clinics; psychiatric hospitals; ambulatory surgical centers; clinical laboratories; hospices; comprehensive outpatient rehabilitation facilities; and clinic, rehabilitation agency, or public health agency providers of occupational therapy, speech pathology, or physical therapy services. This expanded authority has not been used, in part due to lack of relevant national accrediting bodies (127).

20 JCAHO has agreed to perform annual unannounced surveys as required under OBRA-87 if granted deeming authority by HCFA for HHA certification (287).

21 NLN/CHAP fee quoted includes annual fees (based on net revenue according to a sliding fee scale), cost of the initial visit (2 staff On-Site fOr 3 days), plus the cost of two additional survey visits (approximately half the cost of the initial visit) (95).

Box 5-C-The Medicare Peer Review Organization (PRO) Review Process

Prior Review

The physician or provider contacts the appropriate PRO for preauthorization, furnishing the plan of care and any additional documentation required for the review process (183). The first level of review, generally conducted by nurses, involves the application of explicit review criteria that have been developed by the PRO for the particular procedure or service. If the request for authorization fails to meet the initial explicit review criteria, it is referred to a physician reviewer who subjects it to implicit criteria based on his or her own clinical judgment and on professionally recognized standards of care. During this second level of review, the physician reviewer may request additional information from the referring physician. If the request fails second level review (after affording the physician and/or provider an opportunity to discuss the case), authorization is denied (183).

Retrospective Review

Each record identified for retrospective review undergoes five different basic reviews: generic quality screen, admission, discharge, invasive procedure and items/services coverage, and DRG (diagnosis-related group) validation. First-1evel reviewers (usually nurses) use explicit criteria to determine potential quality-related or utilization problems, If initial review uncovers a potential problem the records are referred to a PRO physician adviser for further review (105). Potential quality problems not detected by one of the five reviews (e.g., mismanagement of the case) maybe discovered by the initial nurse reviewer based on his or her medical judgement. In this case, the medical record would also be refereed to a physician adviser. If the initial reviewer can determine that a case failing one of the generic quality screens is not actually a quality problem, the case is not referred to a physician adviser (357).

A physician reviewer conducts a more in-depth examination of the medical record, based on his or her clinical judgment, to determine whether there actually is a problem. The review process also allows the attending physician and hospital an opportunity to discuss the specifics of the case in question. These discussions often reveal unique characteristics of the case that explain why it may have failed the initial screens. Most cases of potential problems are resolved this way (92).

If the physician reviewer determines after the discussions that the care provided was not medically necessary or that it should have been provided in another setting, a payment denial notice is sent by the PRC) tn the beneficiary, physician, provider, and fiscal intermediary. If the physician reviewer identifies a quality of care problem that is not cleared up after discussing the case with the patient's physician, the PRO will initiate appropriate interventions. These interventions may include physician education through a continuing medical education program, a corrective action plan, intensified review of the physician and hospital, or the initiation of a sanction review (357).

on typical patterns of practice within its geographic area or, where appropriate, on national criteria (374).

The retrospective review process uses separate quality screens that focus on potential problem areas and the overall appropriateness of care provided. The quality screens used to review the intervening HHA care received by readmitted hospital patients, for example, address such issues as the adequacy of patient screening and education, the provider's response to any changes in the patient's health condition, whether any deaths occurred within 48 hours of transfer to the hospital, and documentation of the plan for appropriate followup care (375).

Based on the information collected in medical record reviews, PROS produce physician and hospital "profiles" containing information on claims denials, mortality, and confirmed quality problems. The profiles are used to identify patterns of care that deviate from the norm for particular types of providers or deviate from established criteria and standards (350). The identification of an aberrant pattern of care may trigger a PRO's evaluation of a larger sampling of records from the physician or hospital in question. If PROS were to be involved in reviewing HDIT claims, the development and use of such profiles for HDIT providers might be an additional mechanism for safeguarding the quality and appropriateness of HDIT services.

At present, PROS' only involvement in quality assurance for home health is through hospital readmission review and beneficiary complaints (Public Law 99-509).[22] The PRO takes a 25 percent

[22] They do not review intervening care rendered in a physician office setting, emergency room, or any other setting, although emergency mom settings are proposed to be included as an intervening care review setting in the fourth contract cycle for PROS (53).

sample of all hospital readmission for a given year. From that sample, it reviews 20 percent of those readmission that received intervening care in a hospital outpatient clinic, HHA, or skilled nursing facility, obtaining relevant clinical records from the intervening care setting to determine whether the care provided was adequate and appropriate (53). The sampling method and small sampling size, however, limit the usefulness of these data in assessing quality at the individual provider level. Even the Keystone PRO in Pennsylvania, which was the first to review intervening care claims and has had the most experience with the process, had reviewed an average of only one patient per HHA per year in the State as of 1990 (53).

PROS also review HHA claims involving beneficiary complaints, but the flow of complaints to date has been highly inconsistent among States (53). This may be due to lack of beneficiary awareness of the availability of the PRO to investigate such complaints (44). Confidentiality provisions that prevent the PRO from informing the beneficiary of the results of such an investigation may also serve as a disincentive for beneficiaries to lodge formal complaints (53).

Proposed PRO Activities Under the MCCA Benefit

The MCCA called for extensive PRO involvement in oversight of home IV drug therapy services to ensure that care was being provided safely to an appropriate set of patients. Regulations and instructions issued pursuant to the MCCA articulated six areas of direct PRO involvement (54 F.R. 173).

Prior authorization:

1. Prior review of 100 percent of home IV therapy claims until 1993.[23] PROS were to complete review prior to initiation of services for inpatient starts, and within 1 working day of service initiation for outpatient starts.
2. Review of all requests for continuation of home IV therapy beyond the date or number of days specifed in the original request. These reviews were to be completed within 3 working days of the original termination date.
3. Review of all requests for changes of home IV drug therapy during the specified course of treatment, to be completed within 1 working day of the prescribed therapy change.

Retrospective review:

4. Postpayment review of a random 5 percent sample of all paid home IV therapy claims to determine provider and physician compliance with professionally recognized standards of care.
5. Periodic validation reviews of a random sample of claims in which initial approval was granted after the PRO had reviewed medical information via telephone but had not reviewed actual medical records, to validate the accuracy of information given verbally.
6. Prepayment review of any cases where PRO initial authorization was required but had not been completed.

Universal prior authorization for HDIT may not be necessary. The rationale for this requirement under the MCCA was to ensure safety and appropriateness of a relatively new and complicated mode of service delivery through a front-end mechanism. However, as the range of therapies that can be safely and effectively provided in the home setting expands and the volume of claims increases, it may no longer be practical for PROS to perform prior authorization on all claims. Furthermore, some therapies (e.g., certain antibiotic therapies) pose relatively little serious risk to patients. Claims for these might be handled through retrospective review unless HCFA felt there were a potential for mis- or overutilization of home IV antibiotic therapy (e.g., if oral drugs were usually sufficient for the condition but were not covered by Medicare).

Requiring PROS to perform prior authorization for all drug changes during the course of HDIT. services also may be unnecessary. As one alternative, Medicare could implement more limited safeguards, such as requiring additional patient instruction as to potential complications and mandating professional supervision during administration of the first dose of a new drug. Targeted retrospective review of drug changes by either a PRO or an FI could identify problems with particular drugs (or particular providers).

In some circumstances, there may be a need for ongoing review of a patient's HDIT to ensure that the course of treatment continues to be safe and effective for that patient. In the event of future Medicare coverage for HDIT, an appropriate regula-

~ PRO prior review of all home IV claims was mandated under the MCCA until 1993 and left at HCFA's discretion thereafter (44).

Box S-D—Proposed Scope of PRO Review for Home IV Drug Therapy Services Under the Medicare Catastrophic Coverage Act of 1988

From the time it received a request for review of home IV drug therapy services from either a physician or a health care facility, a PRO was to have 8 working hours to determine whether the services were reasonable, appropriate, and necessary for treatment of the patient's condition. Before approving home IV drug therapy service, the PRO was to have determined or to have been assured that:

* the patient's condition was such that inpatient hospitalization was not justified either:
  1) as a continuation of an existing hospitalization, or
  2) as a medically necessary and appropriate admission;
- the patient met the selection criteria specified in the regulations (see **appendix** C);
- the patient and/or caregiver had been or would be sufficiently trained to administer the drugs safely and effectively in the home;
- the patient or caregiver would independently administer at least one dose of the drug under supervision;
* the plan of care developed by the referring physician had enough information to support coverage of home IV drug therapy services;
- the covered drug was being used for one of the indications approved by the Secretary of the U.S. Department of Health and Human Services;
- the drug was medically indicated for treatment of the patient's condition;
- the prescribed dosage of the drug was correct for the patient's height, body weight, and other considerations;
- appropriate periodic monitoring had been or would be performed;
- the drug was not contraindicated;
- the home IV drug therapy services prescribed met professionally recognized standards of care; and
- the intavenous route of administration was the only safe and effective route for the patient.

SOURCES: 1%0 *Review* of Home IV Drug Therapy Services, guidelines issued to PROS by the Health Standards and Quality Bureau, Health Care Financing Administration, September 1989; 54 F.R. 173, Sept. 8, 1989.

tory body might want to identify specific drugs or conditions that warrant a more intense level of ongoing review and require that PROS or FIs perform such reviews.

Finallly, prior authorization of HDIT cases requires the ability for rapid response, since lack of responsiveness can delay hospital discharge or the initiation of therapy. Prior authorization of all HDIT claims within 1 working day might present serious administrative challenges to PROS. FIs might be an alternative body that could evaluate the appropriateness of HDIT on a prior, case-by-case basis. FIs have some experience with current HDIT coverage under the Part B DME benefit and the Part A home health benefit (365) (see ch. 6). Prior review might even be divided between PROS and FIs depending on type of therapy and the potential for its overuse. For example, prior review for therapies with which FIs have limited experience might be placed initially within the domain of PROS until a sufficient base of experience has been obtained to develop explicit review criteria. At that point, responsibility could be transferred to the FI, who could either continue prior review or resort to retrospective review. Alternatively, prior review could be made the responsibility of FIs from the start, with PROS reviewing only a random sample of claims retrospectively. FIs might also be a more appropriate choice than PROS for conducting change-of-therapy review in cases where HCFA deems this necessary.

Before the MCCA was repealed, HCFA had proposed generic quality screens to be used by PROS in prior review of home IV therapy claims (see box 5-D), as well as retrospective quality of care screens (53,167,376). HCFA had also developed diagnostic testing and other special criteria specific to the type of therapy and diagnosis to be used by PROS for review purposes (376).

If Congress were to create a new HDIT benefit, the work begun by HCFA in developing guidelines and screening criteria for prior and retrospective review of home IV therapy could serve as a starting point for the development of final screening criteria. New criteria would be needed, however, if the benefit were to cover alternative routes of parenteral administration, additional drugs, and/or beneficiaries who were not capable of self-care procedures.

Quality Assurance for Beneficiaries Who Receive Care Through Risk-Based Contracts

Under the proposed regulation, HCFA intended not to extend PRO review (either prior or retrospective) to home IV drug therapy services delivered to beneficiaries in risk-based health maintenance organizations (HMOs) or competitive medical plans (CMPs) (54 F.R. 173).[24] HCFA reasoned that:

[B]ecause risk-based HMOs/CMPs already have the clear incentive to prevent unnecessary utilization of covered health care services, it would be largely duplicative and, therefore, wasteful to have PROS use their limited resources to make the same determinations (54 F.R. 173).

Although PRO utilization review activities may have been duplicative of existing HMO/CMP initiatives, it is not clear that PRO quality review would have been duplicative. Because HMOs and CMPs are paid on a per capita basis for the services they render to Medicare beneficiaries, they have incentives to control the utilization of potentially costly services such as HDIT. They do not have as direct an incentive to control the quality of services delivered.

In 1985, Congress mandated PRO review of quality of inpatient and outpatient services provided to these beneficiaries after January 1987 (Public Law 99-272).[25] A recent study by GAO found serious deficiencies in PRO external review of quality of care provided in risk-based HMOs, citing data collection and sampling problems as the major barriers to adequate oversight (355). The GAO study also found that HCFA does not adequately assess the effectiveness of HMO internal quality assurance programs. Although PRO case-by-case review of HMO quality of care is mandated, PRO review of HMOs' internal quality assurance programs is optional and most HMOs have chosen not to subject their programs to PRO review (355). The increasing enrollment of Medicare beneficiaries in risk-based HMOs in recent years (355) makes it all the more important to extend any Medicare HDIT quality assurance efforts (including PRO review) to these plans.[26]

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24 The number of Medicare beneficiaries enrolled in risk-based HMOs more than doubled between 1985 and 1990 (from 383,480 to 1,238,479) (355). See 42 CFR part 417 for a description of Medicare contracts with risk-based HMOs/CMPs.

25 Public Law 99-509 amended this provision, allowing HMOs to contract with organizations other than PROS for quality review and changing the effective date of mandated PRO review to April 1,1987. As of September 1990, despite the allowance of Public Law 99-509, all risk-based HMO quality of care review was being conducted by 30 Medicare PROS (355).

26 HCFA has recently proposed major changes in the PRO review process for HMO/CMP enrollees. The changes, which would be implemented sometime during 1992 or 1993 if approved, include a move away from inpatient hospital claims review toward a more comprehensive review of *all care* delivered over a 12-month period for a random sample of enrollees (46). HCFA has also proposed tbat PROS conduct a more focused review of records of deceased beneficiaries (46).

Chapter 6

COVERING HOME DRUG INFUSION THERAPY: IMPLICATIONS FOR MEDICARE

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Chapter 6

COVERING HOME DRUG INFUSION THERAPY: IMPLICATIONS FOR MEDICARE

Overview

Introduction

Medicare, the Federal Government's insurance program for the elderly and disabled, does not have a home drug infusion therapy (HDIT) benefit. No part of the Medicare insurance plan states that Medicare will pay for the prolonged administration of drugs in the home. Yet Medicare does indeed pay for many of the components of HDIT some of the time, and during the brief period when the Medicare Catastrophic Coverage Act (MCCA) was law, it was explicit Federal policy to extend coverage to HDIT more generally. The repeal of that act has permitted a second look at the implications of such a benefit.

As with most other aspects of HDIT, there is little direct and unambiguous evidence to shed light on what would happen if Medicare covered the therapy. This chapter draws on small studies, the health economics literature, the experiences of private payers and Medicare carriers, the experiences and statements of providers, and the findings of previous chapters of this report to examine the scenario of Medicare coverage and the various ways it might play out.

To do so, the chapter first examines the costs (and benefits) of HDIT from the perspective of the different actors involved-patients, providers, third-party payers, and the health care system as a whole-and discusses some of the factors that affect those costs. It then describes the extent to which Medicare currently covers components of HDIT and related services. Finally, the chapter discusses some of the issues and implications of extending Medicare coverage for the program, its beneficiaries, providers, and technological change.

Summary of Conclusions

- Most patients who have been treated with HDIT find it preferable to hospital inpatient treatment. For them, any additional patient-related burdens of home treatment (in time, travel, etc.) are more than offset by the advantages of a more normal home and work life.
- HDIT can be expensive to provide. Nonetheless, it is widely believed to be cost-saving to patients, third-party payers, and the health care system alike. For the kind of patient most likely to be on such therapy in the past-typically, a relatively young patient on antibiotic therapy who has no need of medical or assistive care other than the infusion-related care-this belief probably holds true much of the time.
- Under other circumstances, however, HDIT is probably often not less costly to the health care system than institutional alternatives. These circumstances are more likely to occur if the patient is unwilling to bear the responsibilities of home therapy; if the patient has additional medical problems or disabilities besides those that necessitate the infusion therapy; if there is no unpaid caregiver able to assist the patient at home; or if the patient's discharge forces a hospital bed to lie empty.
- Despite the lack of a benefit for HDIT, a substantial amount of it appears already to be paid for in some way by Medicare, but this indirect coverage is neither coordinated nor equitably applied. Existing coverage is so fragmented and variable that its extent is impossible to describe with any accuracy. Nonetheless, under current rules, the actual coverage is increasing and will probably continue to do so in the near future, as Medicare's administrative contractors use their discretion to cover drugs as well as the associated equipment, supplies, and nursing care.
- The absence of a coordinated benefit for HDIT limits the extent of the services that are provided. It also limits the ability of Medicare to assess, monitor, or influence the safety, quality, and effectiveness with which HDIT services are delivered.
- Medicare patients are much more likely than other patients to have social or medical circumstances that would require a paid caregiver to administer HDIT. They are also more likely to need additional assistance with daily living activities. Thus, while some Medicare patients

are ideal and self-sufficient candidates for HDIT, many would probably have total home care costs that exceed institutional costs.

- Medicare coverage of HDIT would offer opportunities for enhanced quality of life during treatment for many beneficiaries. It is possible (though by no means certain) that in the long run such a benefit might also be cost-saving to the program. In the short run, however, the addition of this benefit would raise program costs significantly, because Medicare cannot immediately recoup the financial benefits of shorter hospital stays. The extent of the added short-run costs, and the likelihood of long-term cost savings, would depend on the breadth of the benefit and its administration.
- Decisions regarding the exact drugs and conditions to be covered under an HDIT benefit could be made at the statutory, regulatory, fiscal intermediary (FI),[1] or individual physician level. Of these, decisionmaking placed at the regulatory or FI level are the most consistent with existing Medicare coverage decisions. Compared with FI decisionmaking, coverage decisionmaking at the regulatory level permits more consistency but less rapid accommodation of new drugs and drug protocols that might be appropriate for home use.

The Costs of Home Drug Infusion

The costs of HDIT depend on the perspective of those paying them. For the provider, costs are the costs of inputs-supplies, services, equipment, drugs, and administrative overhead. For payers, costs are payments for the service and administrative time for the benefit. For patients, costs—and benefits-are in dollars, time, and ability to participate in other activities. For the health care system as a whole, costs are overall resource and opportunity costs. HDIT is frequently cited as being cost-saving (see below), but the extent to which it is so depends very much on the context in which it takes place and the perspective from which cost savings are analyzed.

On its face, the literature regarding the costs and cost-effectiveness of HDIT is extremely positive. With very few exceptions, published studies conclude that HDIT is less expensive than institutional therapy for presumably equivalent benefit. Since 1978, when the first two reports appeared, at least 17 studies have reported that charges for antibiotic infusion patients treated at home were less than those for hospital-treated patients (16,78,101,106, 106a,119,136,148,182a,187,188,267,268,278,324,325, 335). The average reported savings per home patient in these studies ranged from $510 to $22,232 (22).

A problem in using these studies to infer cost-effectiveness of HDIT is that most use only provider charges, rather than resource costs, for their comparisons of home and hospital therapy. In addition, in many of the studies, hospital and home patients were apparently unmatched except for the general type of therapy. Hospital charges often included surgery and other inpatient procedures that had no home equivalents, and in some cases, hospital charges were simply rough estimates.

A more rigorous study of once-a-day intravenous (IV) antibiotic administration for osteomyelitis was published in 1986 (101). It, too, found that HDIT resulted in lower per-patient expenditures. Patients in the study were assumed to be entirely self-administering; no allowance was made for outpatient nursing. Collectively, then, the existing literature shows that, for carefully selected patients, charges for home care can average considerably less than charges for hospital care.

The actual resource costs of care, however, do not necessarily bear any relationship to charges. In fact, it is the difference in the perception of what costs are relevant, and changes in who is receiving home care, that explains why HDIT has not diffused even more rapidly despite the extensive literature on its savings potential. The following section discusses these factors.

Provider Costs

HDIT is not inexpensive to provide. It requires special expertise on-the part of nurses; it requires substantial amounts of pharmaceuticals and clinical pharmacy services; and it may require equipment rental as well as a multiplicity of supplies. Once begun, it cannot be abandoned without institutionalizing the recipient or endangering the patient's health. Thus, placing a patient on HDIT requires a substantial financial commitment on the part of the provider. There are no studies of actual provider

[1] Fiscal intermediaries (Part A intermediaries or Part B carriers) are Medicare's local administrative agents.

costs of finishing this service; only anecdotal information is available. One HDIT provider, for instance, believes its average costs of providing all drugs, services, and supplies for IV antibiotic therapy to be roughly $4,000 per month (367).

Costs probably vary considerably among providers. Health care worker wages, for example, are usually higher in urban than in rural areas (48 F.R. 39752). Wages for nursing services also vary among providers depending on the qualifications the provider requires of the nurses. The exclusive use of registered nurses (RNs) with extensive IV therapy experience, for example, is more costly (and possibly of higher quality) than the use of RNs with limited experience who perform both IV and other home health nursing services, because the more highly skilled nurses command higher salaries (364). One survey of infusion specialty companies found that their specialist nurses earned an average of $17.44 to $20.15 per hour, depending on experience (256).

Costs of supplies and equipment can also vary considerably among providers for any given therapy. Some providers, for example, use infusion pumps for almost all the therapies they provide (364). Others use less expensive gravity drip systems to deliver many antibiotics (364). Even among pumps, there can be great variation in costs (table 6-l), with the choice of which pump to use dependent on type of therapy, provider experience, purchasing arrangements, physician and patient preference, and patient characteristics.

Providers' drug costs vary tremendously as well, even within a single category of drugs such as antibiotics. Different antibiotics can have dramatically different average prices. Even for a single drug, providers' costs of acquiring the drug vary depending on their purchasing power (60,331).

The kinds of patients seen will affect both supply and nursing costs. Providers with a high cancer or AIDS[2] caseload, for example, may spend more per patient than other providers because these patients often require multiple therapies and the administration of highly toxic drugs that require pumps to be administered safely (see chs. 2 and 3). Similarly, providers who serve large numbers of elderly or disabled patients are likely to have higher nursing costs per patient than other providers, because these individuals may need more assistance with their therapies and other health and personal care needs (see ch. 3).

Table 6-l—Prices for Ambulatory Infusion Pumps: Examples From Two Manufacturers, 1991

Manufacturer/pump	Pump price[a]
Pharmacia Deltec	
CADD-HFX	$2,595
CADD-PIUS	3,395
CADD PCA2	3,495
CADD-TPN pump	3,595
CADD-TPN system	3,995
Ivion Corp.	
Walkmed 300	1,860
Walkmed 410	2,095
Walkmed 420	2,695
Walkmed 430	2,695
Walkmed 440	3,095
IntelliJect@	5,400

[a]Prices are those quoted to the Office of Technology Assessment by the manufacturers in October 1991. It is possible that the actual prices paid by some providers are lower than the prices listed here (e.g., if the providers obtained discounts from the manufacturers).

SOURCES: M. Moraczewski, Pharmacia Deltec, St. Paul MN, personal communication, Oct. 7, 1991; R.P. Nelson, Ivion Corp., Broomfield, CO, personal communication, Oct. 7, 1991.

There may be some tradeoff between nursing and supply costs. The use of a preprogrammed pump, for example, may allow an elderly patient to go home on therapy without the need for a paid nurse to administer each dose. The actual extent to which more sophisticated drug delivery systems may reduce nursing costs, and for which patients, is undocumented and apparently unknown.

Payer Costs

The costs of HDIT to a third-party payer-e.g., Medicare, Medicaid, or private insurance-are the amount that the insurer pays for the therapy *and any associated health care services necessary to provide it.*[3] *This* amount may simply be the providers' charges for the therapy and associated services, minus any coinsurance or deductible paid by the patient. Alternatively, the insurer may pay on some other basis, such as a fee schedule or a rate negotiated beforehand with the provider.

Much of HDIT's early success and rapid diffusion into the health care system has derived from

[2]Acquired immunodeficiency syndrome.

[3]In some cases—e.g., in some health maintenance organizations—the provider and the insurer maybe the same entity. In this case, the insurer's costs are simply the costs of providing the service.

providers' ability to convince insurers their payments will be less for home than for hospital therapy. But in 1992 this is not always the case, despite the evidence that home care charges have historically been lower.

Insurers' home care payments are sometimes higher than hospital payments for two reasons. First, the most important contributor to the lower historical charges for home infusion is the replacement of paid room, board, and labor in the hospital with their unpaid equivalents in the home. All of the studies that reported lower charges for HDIT required that home patients be able and willing to carry out their infusions with the help of a family caregiver. But HDIT in the 1990s is by no means limited to self-infusing patients (250,364), and total home charges for patients who require paid assistance may exceed hospital charges for equivalent care (204). This may be particularly true if, in order to substitute home for hospital care, the patient needs not only assistance with the infusion but help with other activities as well (e.g., dressing and bathing).

Second, the relationship between payments and charges differs for hospital and home therapy. Medicare, Medicaid, and private insurers now often pay hospitals much less than actual charges.[4] But insurers that pay directly for HDIT often still do so on the basis of home provider charges, because they have little other basis for establishing payment rates (55). Consequently, according to insurers, payment for HDIT can sometimes exceed payment for equivalent hospital care even for the most self-sufficient patients.

For example, one insurer told the Office of Technology Assessment (OTA) that it had received claims for a patient with Lyme disease in which the charge for self-administered home IV antibiotic therapy was over $650 per day. Based on its hospital payment experience, the insurer believed that hospital care for this patient would have been considerably cheaper than home care at the charged rate (367).

The difficulty in realizing cost savings to the payer is particularly acute for third-party payers that reimburse for hospital inpatient care at a fixed rate per patient discharged. In this case, the hospital payment remains the same regardless of whether the patient is discharged home after a few days or remains hospitalized for several weeks. From the payer's perspective, home care payments simply add to, rather than substitute for, hospital payments under such a system (243). Only when hospital care is averted altogether can the payer reduce its costs.

Patient Costs

Patient-associated costs of HDIT fall into three categories. First, and most obvious, are direct *medical costs. In the* extreme, when no third-party coverage applies, these costs include the purchase prices for all of the products and services directly related to the therapy. Because these costs are very high for most patients, HDIT is probably rarely provided to such patients except as charity care. When the patient's insurer does cover home therapy, the patient's direct medical costs include any insurance copayments (i.e., coinsurance and deductibles) and any provider charges uncovered by the insurer (e.g., charges greater than the payer's allowed charge and charges for any luxury or nonprescribed items).

Nonmedical costs (e.g., food, electricity, and transportation costs) can be equally important to home patients. Some of these, such as food, become "medical costs" and are covered by insurance when provided in a hospital. Finally, patients on prolonged infusion therapy also bear *indirect costs* associated with the therapy, such as time lost from family responsibilities and leisure activities, lost income, family stress, and psychological discomfort.

It is the lessened indirect costs often associated with HDIT that account for its popularity with patients. Patients with strict school, work, or home responsibilities (e.g., caring for another family member) can be very vocal and articulate in their preference for HDIT (364). In studies reporting on patient satisfaction and activities during HDIT, most home patients were able to resume their normal activities while on treatment (106,188). Even those without employment or other outside commitments may find home infusion attractive because it permits the patient to engage in outside recreational activities and a normal social life (364). No studies have

[4] Medicare and Medicaid have paid less than actual charges for many years. More recently, the increase in managed-care programs such as preferred provider and health maintenance organimations (which together make up over one-fourth of the group insurance market) (150) means that many private insurers also receive substantial discounts off of hospitals full charges.

been performed on the extent to which elderly patients requiring infusion therapy prefer one site of care over another, but there is no reason to think they would value the relative freedom of home care less than most other patients.

Costs to the Health Care System

Whether paying for HDIT costs more or less to the overall health care system than not paying for this service cannot be answered by examining either provider, payer, or patient costs in isolation. HDIT is cost-saving to the system if (and only if) the net health care resources required to provide this service, and any adjunct services needed at home, are fewer than those required to provide equivalent therapy and services in alternative settings.

The comprehensiveness of this requirement is critical. *It is the total package of care required by a patient in order to be treated at home just the infusion therapy-that must be compared with care in alternative settings in an evaluation of relative health system costs. If* a patient needs help with bathing and N site dressing (bandage) changes in order to be treated at home, the costs of providing those home services must be counted as part of the costs of being able to receive HDIT. Depending on the way benefits are defined and paid, HDIT can be cost-saving to any individual payer without necessarily saving health system resources overall, and vice versa.

The three basic settings for drug infusion therapy that are alternatives to the home are hospitals, while the patient is an inpatient; ambulatory care settings, such as outpatient clinics and physician offices; and skilled nursing facilities (SNFs) (including self-defined subacute care facilities). There are no studies of the resource costs of providing drug infusion therapies in any of these settings. However, it is possible to explore some of the factors that influence relative costs under different circumstance.

Need for Professional Services

In the extreme, if a patient needs 24-hour skilled nursing in order to be able to receive drug infusion therapy at home, the home is highly unlikely to be a cost-saving setting for treatment. In this instance, the nurse can care for only a single patient, a situation that is very resource-intensive and that can be more expensive than most hospital care (204,362a).

In contrast, the home is likely to be a relatively efficient setting for a patient who requires no professional care at all except for the initial training. Since the training itself is a resource cost not incurred by institutionalized patients, the relative cost savings for such patients increases with the length of time on therapy. This potential for great savings over time for independent and relatively healthy patients was one of the spurs behind the decision by Medicare in 1977 to pay for home therapy for patients requiring long-term total parenteral nutrition (TPN) (359).

Cost of Travel and Care Coordination

Home therapy, in contrast to inpatient- or clinic-based therapy, requires a considerable amount of provider time spent in activities other than direct patient care, such as travel between patients and coordination among relevant providers (physician, pharmacist, nurse, etc.). Where the costs of conducting these activities are high, home care may be relatively more resource-intensive. For example, if a patient needs professional supervision for a 4-times-a-day infusion regimen, requiring multiple daily trips by the nurse, home care may be more costly to the health care system than equivalent care provided in an SNF. Patients with many complex health care needs, of which infusion therapy is only one, may be similarly less expensive to care for in a health care setting that can offer the array of needed services on-site.

Providers of clinic-based outpatient infusion therapy maintain that this setting is more efficient than home care for treating many patients (340,340a). The ability of outpatient clinics to maintain all needed services on site, with personnel in constant communication, suggest that this assertion may well be true for at least some patients.

Institutional Occupancy Rates

Treating patients at home rather than in the hospital cannot be cost-saving to the health care system if hospitals are unable to either eliminate beds and associated services or put the beds and services to better use (e.g., by transferring into the now-open bed a patient previously being treated in the intensive care unit). Where hospitals have unoccupied beds and underutilized staff, continuing treatment in the hospital may well be less expensive

Box 6-A—The NAIT Survey

The National Alliance for Infusion Therapy (NAIT), an association of "providers and manufacturers of home infusion services, equipment, and products," sponsored a survey of data from nine of its members in 1990. The survey' goal was to "identify types of available data and obtain preliminary information about industry and patient characteristics.' It included the following components:

1. National ***patient census. The*** contractor performing the survey (Coopers & Lybrand) collected cross-sectional data for March and September 1990 to obtain a complete census of all home infusion therapy patients considered "on service" at that time in eight participating companies. This census (42,700 patients on Sept. 30, 1990) was then analyzed according to variables of interest (e.g., geographic location).
2. *Patient-specific data sample.* From a stratified sample of 86 branch offices of companies participating in the survey, the contractor then sampled 2,506 patient records to identify patient-specific demographic, clinical, service, and therapy information. Patients were selected for the sample only if they received one or more of the following infusion therapies during the 2-week sample period: antibiotics, antineoplastics, pain management, total parenteral nutrition, and enteral nutrition.
3. *Patient education survey. The* contractor separately surveyed a small sample of previously hospitalized patients who were receiving services from participating companies regarding the infusion-related education and training they received in the hospital before discharge.
4. *Site visits* to four branches of three companies and one corporate office to obtain operation and service delivery information.
5. *A review of the published literature* regarding home infusion therapy services, costs, and wages for skilled employees.
6. *Longitudinal data* for a subset of all previously surveyed patients who were discharged from home infusion service during the period Sept. 9, 1990 through May 31, 1991. (Late reporting and incompleteness made these data of questionable reliability.)

SOURCE: A.K. Parver and K. Lind, National Alliance for Infusion Therapy, Washington, DC, memorandum to E. Power, Office of Technology Assessment, Oct. 30,1991.

to the health care system than treating that patient at home (at least in the short run). Conversely, if institutional beds are fully occupied, home care becomes a relatively more efficient setting, because the alternative is to build more institutional beds.

HDIT Coverage by Non-Medicare Payers

Most health care third-party payers cover HDIT at least some of the time. Coverage increased substantially during the 1980s, as the technology became more developed, providers became more adept at convincing payers of its worthiness, and payers became more familiar with it. In a 1990 survey of records of some infusion companies that are members of the National Alliance for Infusion Therapy (NAIT), less than 4 percent of patients had no third-party coverage of any kind for their therapy (257). (Box 6-A describes the NAIT survey.)

Private Insurers

Most HDIT is paid for through private insurance. Several providers who specialize in home drug infusion (as opposed to TPN) report anecdotally that over three-fourths of their patients have private third-party coverage (83,343).[5] The NAIT survey found that almost 64 percent of patient records sampled listed private insurance as the payer and an additional 14 percent had a combination of private insurance and Medicare (256).

Similarly, most private insurers cover HDIT to at least some extent. A 1987 *survey* of coverage for home IV antibiotic therapy found that of 50 Blue Cross/Blue Shield programs, 47 covered this service, although 34 required that it receive prior authorization before coverage commenced (21). This survey likewise found that most commercial insurers and all of the 19 responding health maintenance organizations covered this therapy, with about

[5] **Because Medicare covers TPN, providers specializing in this form of infusion therapy would be expected to have a higher proportion of Medicare patients (and a lower proportion of privately insured patients) than those specializing in HDIT.**

half of each group requiring prior authorization (21). These results, now 4 years old, probably understate current coverage; the continued expansion and financial well-being of the HDIT industry suggests that coverage for the therapy is widespread.[6]

Medicaid

Medicaid is a federally aided, State-administered program that provides medical assistance to roughly 26 million low-income people (114). Although the Federal Government sets some minimum standards, the actual services offered by individual State Medicaid programs vary widely among the programs.

All State Medicaid programs cover the basic components of HDIT in some fashion (although they do not necessarily pay generously). Durable medical equipment (DME) and home care services for adults, for example, are federally mandated benefits under the program. Prescription drugs are optional, but as of 1990 all 50 States and the District of Columbia covered them (373).

More comprehensive coverage of HDIT, however, is not so universal. A 1987 survey of the 50 State Medicaid programs, sponsored by Hoffmann-La Roche, found that 48 of the 50 States paid for home IV antibiotic therapy (21). Of these 48 programs, 29 required that the service receive prior approval before it would be covered. At least one Medicaid program has documented that HDIT has been cost-saving to the program (box 6-B).

Box 6-B—Home Infusion Therapy in the Colorado Medicaid Program

A review of claims for home infusion therapy **submitted** to Colorado's Medicaid program found satisfactory results of this coverage for that program. Researchers found that 61 patients were treated at home, based on claims submitted over a 26-month period. Most of these patients were treated with anti-infective drugs. The remainder received either other infused drugs or total parenteral nutrition (TPN) (85).

program savings for the period were estimated to be at least $125,000 (1988 dollars). The program resulted in a significant shift of Medicaid resources, from hospital spending (which decreased by au estimated $430,000 due to the program) to expenditures for nonhospital pharmacy services (which increased by nearly $100,000). Anti-infective therapy was the greatest overall contributor to savings, due to its large share of patients, while pain management resulted in the greatest per-patient savings. In this study, home TPN was found to result in little or no program cost savings (i.e., it did not reduce Medicaid expenditures) (85).

CHAMPUS

The Civilian Health and Medical program of the Uniformed Services (CHAMPUS), operated by the Department of Defense, is an example of another government health care program that covers HDIT in at least some cases. CHAMPUS pays for the medical care needed by dependents of active and retired military personnel when that care cannot be obtained from a military hospital. The program covers home infusion therapy both under its basic benefit package and through two ongoing home health care demonstration projects. Coverage is generally broad, but it is probably somewhat erratic in its implementation due to the individualized nature of many coverage decisions.

CHAMPUS basic home health benefits include medical equipment, skilled nursing care, drugs and medical supplies, and physician visits. The program has little formal policy regarding what types of home infusion therapies are covered; all decisions are made on a case-by-case basis, and informal coverage policies (mostly in the form of specific exclusions) are based on accumulated claims experience (20). However, coverage for HDIT appears fairly broad. Except for beneficiaries requiring custodial care (to whom limits on nursing services apply), unlimited home health visits to CHAMPUS beneficiaries are covered if they are medically necessary and if the patient is either "homebound" or services are otherwise determined to be needed in the home.[7] Infused drugs are covered, but only if they are approved by the Food and Drug Administration

[6] The financial well-being of the HDIT market is suggested by the fact that, according to market analyst estimates, industry revenues grew by over 30 percent per year between 1986 and 1988 and were predicted to continue to grow by over 25 percent per year through 1991 (275). Companies likewise continue to perceive the HDIT industry as a growing one, and of the top 10 companies in the home care industry (defined by total revenue), 7 derive at least a quarter of their revenue from home infusion therapy, including HDIT (392).

[7] CHAMPUS has no working definition of "homebound," and fiscal intermediaries may be applying the restriction rather liberally (20).

(FDA) for both the particular route of administration and the particular condition (19).[8]

In contrast, under the ongoing demonstration projects, drugs may (on a case-by-case basis) be covered for unapproved uses if they are widely used for those purposes (269).[9] In general, the demonstration projects require that a patient have an alternate caregiver in order to receive home infusion therapy. However, CHAMPUS has paid for additional assistive services on occasion (269).

Current Medicare Coverage of HDIT

Applicable Existing Benefits

Medicare, the Federal Government's health insurance program for aged and disabled individuals, has no defined benefit that covers HDIT. Infusion therapy of any kind has been considered in the past to be an institutional rather than a home service. Even TPN, which has been covered by Medicare since 1977, is covered under the prosthetic device benefit (as a replacement for the digestive system) rather than as a home infusion therapy benefit.

Nonetheless, there are a number of existing benefits under which patients can get certain components of drug infusion therapy covered at home. The total number of Medicare patients who receive some coverage for home infusion therapy is unknown but probably extensive. However, the coverage that exists is also highly fragmented, nearly always incomplete, and varies enormously depending on the location and circumstances of the patient.

Medicare is separated into two parts: Part A, which covers hospital, skilled nursing facility, home health, and hospice care; and Part B, which covers physician and related services, hospital outpatient services, nonhospital laboratory services, and medical equipment and supplies.[10] Existing benefits that currently serve as "back door" mechanisms for HDIT coverage include:

1. Part B DME benefit,
2. Part A home health benefit,
3. Part B diagnostic laboratory services benefit,
4. Part B physician services benefit,
5. Part B hospital outpatient benefit, and
6. Part A hospice benefit.

Each of these benefits and its relation to HDIT is described below.

Part B Durable Medical Equipment

The Medicare DME benefit is the most broadly available mechanism through which Medicare covers some of the components of HDIT. To be eligible for this benefit, a beneficiary usually need only have a physician certify that the equipment: 1) is furnished to that person in his or her home,[11] and 2) is medically necessary to ameliorate illness or injury or to improve functioning of a malformed body part. Infusion pumps and IV poles qualify as DME.

Medicare also covers medical supplies and accessories necessary for the proper functioning of the equipment (74). Thus, supplies such as tubing, needles, and alcohol swabs would be covered when a pump is covered.

Equipment must be capable of withstanding repeated use to qualify as DME. Single-use infusion control devices (e.g., elastomeric infusers-see ch. 3) do not qualify. Also, equipment with certain convenience or luxury features are covered in full only if those features are deemed medically necessary for the patient's condition (74). Thus, Medicare presumably would not cover a sophisticated infusion pump if the drug to be infused could be delivered safely and effectively through a less expensive gravity drip system. Furthermore, because a gravity drip system (with the exception of the IV pole) is not considered DME, related medical supplies would usually also be excluded from coverage in this instance.

The coverage of supplies and accessories related to the DME explicitly includes "drugs and biologicals that must be put directly into the equipment to assure proper functioning of the equipment" (74).

[8] CHAMPUS does not cover dregs for unapproved uses; for example, the FDA has not approved terbutaline for use in preventing preterm labor, so it is excluded from CHAMPUS coverage (20). The only exception to this general policy is that, under a proposed and soon to be final rule, CHAMPUS will cover class III investigational cancer drugs listed by the National Cancer Institute (20).

[9] For example, CHAMPUS does cover home-infused terbutaline for high-risk obstetric patients under the demonstration program. They have experience with about 60 patients, and staff believe the therapy to be effective in prolonging pregnancy (269).

[10] Home health services can also be covered under Part B for beneficiaries who are ineligible for Part A benefits.

[11] For the purposes of this benefit, a "home" is defined as the patient's place of residence, but the definition excludes institutions or distinct parts of institutions that meet the basic definition of a hospital or a skilled nursing facility.

Box 6-C—Defining "Homebound" Under the Medicare Home Health Benefit

For much of Medicare's history, "homebound" was written in the statute as "confined to the home" and appeared at only two places in the Social Security Act (sections 1814(a) and 1835(a)). Over the years, the Health Care Financing Administration (HCFA) attempted to clarify the definition through guidelines and examples in the Medicare Intermediaries' Manual. The guidelines essentially restricted qualifying beneficiaries to those unable to leave the house by any means to get medical care, although the manual specified a few exceptions (e.g., trips to church, trips to the doctor for medical care that couldn't be delivered at home) (379). Still, intermediaries' interpretations of "homebound" were apparently highly varied (167).

The omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) attempted to further clarify the meaning of "homebound" by specifying in statute that:

> . . . an individual shall be considered to be 'confined to his **home' if the individual has a condition, due to an illness or in., that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be** bedridden to be considered 'confined to his home,' the condition of the individual should be such that there exists a normal inability to leave the home, that **leaving home requires a considerable** and taxing effort by the individual, and that absences of the **individual** from home are infrequent or of relatively short duration, or are attributable to the need to receive medical treatment" (SSA secs. 1814(a), 1835(a)).

Despite this effort to bring some uniformity to the application of the "homebound" restriction, continued ambiguity in the definition of "confined to his home' will most likely lead to continued differences in intermediary interpretation and practice. HCFA intends to publish regulations that attempt to explain the new statutory language in more detail (167).

The interpretation of this clause, however, is left to the discretion of the FI (i.e., the Part B carrier) (155). To clarify what drugs might be appropriately covered through this provision, the Health Care Financing Administration (HCFA) inserted language in the Medicare Carriers Manual that instructs carriers to cover the cost of external infusion pumps *and associated drugs* when used for the administration of:

- deferoxamine to treat acute iron poisoning or iron overload;
- heparin to treat thromboembolic disease and/or pulmonary embolism (in institutional settings only);
- antineoplastic therapy to treat liver cancer patients who cannot or will not undergo surgical treatment; and
- morphine to treat cancer patients for intractable pain (378).

This language neither requires nor prohibits carriers from covering other drugs under this same general rubric .[12]

Part A Home Health Services[13]

The Medicare home health benefit is a source of coverage for skilled nursing services associated with home infusion for Medicare beneficiaries. To be eligible for Medicare-covered home health services, however, a beneficiary must be "confined to his home'—i.e., unable to leave his home without the assistance of another person or a supportive device (379). The legislative definition of "confined to his home' has been broadened in recent years (see box 6-C). However, it is still both fairly restrictive and somewhat ambiguous, and there is still variation among Medicare intermediaries in interpretation of the rule (167).

The homebound requirement effectively eliminates a large number of the least disabled patients on drug infusion therapy from any nursing coverage offered under the home health benefit. For example, patients who are otherwise healthy and nondisabled but require continuation of an 8-week course of antibiotic therapy would not qualify for any home health services because they are not homebound.

12 HCFA does explicitly prohibit coverage of external infusion pumps for the subcutaneous administration of insulin to diabetic patients (378).

13 "Home health services" are covered under Part A unless the beneficiary has exhausted his or her Part A coverage, in which case coverage is under Part B (74).

Beneficiaries eligible for home health benefits also must be under a physician's written plan of care and must be in need of either part-time or intermittent skilled nursing care or skilled physical or speech therapy services (379). Nearly all patients requiring home infusion would meet this qualification. Thus, most infusion patients who were also homebound would be eligible for other home health benefits not related to the infusion therapy as well.[14]

Two home health benefits are especially relevant to HDIT patients. These are:

- *Part-time or intermittent skilled nursing services* provided by or under the supervision of a registered nurse (RN) (379). Patients qualify if they need up to 28 hours per week of skilled nursing and home health aide services combined at less than 8 hours per day, or up to full-time (8 hours per day) on a temporary basis (up to 3 weeks). The need for services up to 35 hours per week of skilled nursing and home health aide services combined at less than 8 hours per day (or on less than a daily basis) may be approved on a case-by-case basis (379). Through this benefit, most skilled nursing services required for HDIT would be covered.
- *DME and medical supplies.* Covered supplies include presumptively medical supplies (e.g., needles, wound dressing supplies) as well as ordinarily nonmedical supplies that are deemed necessary for the patient's medical condition (e.g., lotions or soaps that serve a particular therapeutic purpose). Unlike the part B DME benefit, drugs and biological are specifically excluded from DME provided under the home health benefit (379). Nonetheless, this benefit permits the rental or purchase cost of an infusion pump and all HDIT-related medical supplies except the drugs (e.g., tubing, catheter replacements, dressing supplies, alcohol swabs) to be covered.

The home health benefit also covers:

- skilled physical, speech, and occupational therapy services,
- part-time or intermittent services of a qualifed home health aide,[15]
- medical social services,[16] and
- home medical services of residents and interns in approved teaching programs with which the home health agency is affiliated (74).

All covered services must be furnished by or under arrangement with a Medicare-certified home health agency (HHA) (74).

Part B Diagnostic Laboratory Services

Medicare's Part B diagnostic laboratory services benefit covers nonhospital diagnostic laboratory services that are ordered by a physician, including laboratory tests to monitor the status of an HDIT patient (74,378).[17] Skilled health professional services required to obtain laboratory specimens (e.g., a lab technician to draw blood) and travel costs of laboratory personnel for the purpose of collecting specimens from homebound persons are also covered (378).

Part B Services Incident to a Physician's Services

Services and supplies (including drugs and biologicals that cannot be self-administered[18]) furnished incident to a physician's professional services are covered under Part B of Medicare. Nonphysician services (e.g., nursing services) covered under this provision usually must be performed under the direct supervision of the physician by individuals under that physician's employ (378).

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14 The NAIT survey found that 12 percent of all patients in its sample were nonambulatory (and thus might qualify as homebound) (256). The proportion of elderly patients on HDIT who might qualify is probably considerably higher, since most patients in the NAIT sample were under age 65.

15 'rhepww of home health aide visits must be to provide hands-on personal care or services necessary for the health or treatment Of the beneficiary (e.g., simple dressing changes, assistance with oral medications). Services of a home health aide are not considered reasonable and necessary if there is a family member or other caregiver available and willing to perform them; however, it is customary to presume that no caregiver is available unless the beneficiary or a family member indicates otherwise or the home health agency has knowledge to the contrary (379).

16 Examples of medical social services include: counseling services, community resource identification, assessment of resource coordination, and assessment of social and emotional factors related to the beneficiary's condition and treatment (379).

17 A clinical laboratory that is part of a hospital is considered an independent laboratory when it provides services to nonpatients (378). If the same hospital laboratory provides services to the hospital's outpatients, such services are covered under the Part B outpatient hospital services benefit (74).

18 Intravenously administered drugs are generally not considered by HCFA to be @f&-" tered drugs (378).

In certain unusual circumstances, however, Medicare can waive the direct supervision requirement.[19] Specifically, for homebound patients who live in areas not served by any Medicare-certified HHA, Medicare will cover a number of skilled services when provided by nonphysicians, including injections, venipuncture, dressing changes, and patient training activities (378). HCFA has no information regarding the extent to which services are billed under this waiver (76,143). The increase in the number of certified HHAs (from 2,212 in 1972 to 5,673 in 1990) (353), however, suggests at least that the need for such a provision has decreased.

Medicare coverage of services furnished incident to a physician's services are more commonly relevant to infusion services in the context of outpatient infusion. Through this coverage rule, Medicare covers the nursing services and supplies for infusions performed in physicians' offices. Some carriers apparently restrict such outpatient infusion coverage, however. For example, an IV antibiotic provider in the State of Washington reports that its carrier will cover office-based infusion only for certain medical conditions (146).

Part B Hospital Outpatient Services

As with physicians' offices, hospital outpatient departments already qualify for payment for their various nursing activities and medical supplies, and outpatient infusion provided in this setting is reimbursable. Medicare covers laboratory services, durable medical equipment, visits, medications, and medical supplies provided in hospital outpatient departments (273). Furthermore, payment for most services in this setting is on the basis of reasonable costs, making it potentially financially attractive to hospitals able to organize and maintain an outpatient clinic.

Through this mechanism, Medicare may cover not only infusions performed in the clinic itself but the costs of visits for skilled nursing services (e.g., catheter site changes) when a patient is performing the daily infusions at home. The extent to which the benefit is used for either purpose is unknown.

Box 6-D—Services and Supplies Covered Under the Medicare Hospice Benefit

Supplies and services covered under the Medicare hospice benefit include:

- nursing care;
- medical social services;
- physicians' services;
- counseling services for the patient and familly members;
- short-term inpatient hospice care;
- drugs and biological that are used primarily for pain and symptom control;
- medical equipment and supplies related to pain and symptom management;
- physical, occupational, and speech therapy; and
- home health aide and personal care services (including personal comfort and custodial care items as necessary).

Nursing and home health aide services are covered on a 24-hour basis only during periods of crisis.

SOURCE: Commerce Clearing House, Inc., *Medicare and Medicaid Guide* (Chicago, IL: CCH, Inc., 1990).

Part A Hospice Care

Terminally ill patients (those with a life expectancy of 6 months or less) are eligible for the Medicare hospice benefit. This benefit focuses on palliative treatment, symptom control, and home care rather than on curative treatment. When a beneficiary elects hospice care, he or she becomes ineligible for most other Medicare benefits.[20]

Hospice care must be provided by a Medicare-certified hospice program. Hospice care services and supplies (see box 6-D) are covered by Medicare if they are reasonable and necessary for the palliation or management of the patient's terminal illness and are included in a written plan of care that is reviewed periodically by the patient's physician. The hospice program must provide all these services directly or through arrangements with other approved entities.

Any home infusion services provided by the hospice are covered under a daily rate. Hospices may

[19] The services must still be provided under general physician supervision. "General supervision" requires that the service(s) be ordered by the physician, that the physician maintain contact with the professionals performing the service(s), and that the physician maintain professional responsibility for the service(s) (378). (In contrast, "direct supervision" requires that the physician be on site.)

[20] Services of such a physician the patient's attending physician who is not an employee of the hospice continue to be reimbursable under Medicare Part B (74).

be discouraged from providing such services either because they are too costly, too complicated to provide, or both (26). Some hospices, for example, do not accept patients who are on TPN (30). (Although TPN is covered under the Part B prosthetic device benefit, beneficiaries who have elected the hospice benefit are no longer eligible for such coverage.) The bulk of home infusion therapy provided under the hospice benefit is believed to be for pain management (26). Pain management administered by infusion pump is considered a "high-cost" service by providers, and although hospices generally prefer less costly alternatives, they will generally pay for a pump system if it is requested by the physician (26).[21]

The Extent of Current Medicare Coverage of Home-Infused Drugs

The primary means by which Medicare currently covers HDIT are the home health benefit, which enables homebound persons to receive coverage for infusion-related nursing, and the DME benefit, which permits Medicare beneficiaries who need them to receive infusion pumps and related supplies. It is the latter benefit that allows patients to receive some drugs, with the extent of drug coverage dependent on the Medicare carrier's discretion. These two complementary benefits can, at times, enable a Medicare patient to receive reasonably comprehensive (but uncoordinated) home infusion benefits. The patient, if homebound, may qualify for the home health benefit through the need for intermittent infusion-related nursing, while billing for drugs, equipment, and supplies through the Part B DME benefit.

To assess the extent to which carriers actually cover home-infused drugs through the DME benefit, OTA conducted a survey of all 43 carriers in the United States.[22]

As of February 1991, all of these carriers had policies to cover at least the three drugs explicitly permitted by HCFA for home treatment of specified conditions: morphine for intractable cancer pain, antineoplastic therapies for certain cancers, and deferoxamine for iron overload. Seventeen carriers covered only the drugs and conditions specified by HCFA, and some placed additional explicit restrictions on coverage (e.g., treatment was covered only it begun in a health care setting). At the opposite extreme, however, many carriers covered not only the drugs permitted by HCFA but a wide variety of other drugs as well. For example, 24 carriers reported that they at least sometimes cover analgesics other than morphine; 18 at least sometimes covered antibiotics; and 3 carriers covered dobutamine (365).

A few carriers even reported covering, through the DME benefit, certain drugs that are *not* administered via infusion pumps. One carrier covered antibiotics when administered through a gravity drip system, and one covered hydration therapy in terminally ill patients when the therapy was administered by gravity drip (365).[23]

The results of this survey prompt two conclusions. First, there is clearly great variability in DME coverage policy among carriers, from carriers who cover only the HCFA-listed drugs under the most stringent conditions to carriers who cover even drugs not administered through a pump. Second, the amount of HDIT that is already being covered by Medicare is significant and is increasing rapidly. Both the categories of drugs that carriers are willing to cover and the number of claims for drugs in those categories appear to be rising.

Antibiotics and dobutamine coverage policies present striking examples of the rapidity with which coverage-and claims-are increasing:

- Three of the 18 carriers that covered at least some antibiotics had begun doing so only very recently, and one noncovering carrier was considering extending coverage to antibiotics at the time of the survey.
- Seven carriers said that claims for antibiotics were frequent and submitted in increasing numbers.
- Of the three carriers that said they would cover dobutarnine at home, one had yet to see a claim

21 The issue of high-cost services provided by hospices is currently Waler examination at Project HOPE as part of a congressionally requested study (26).

22 These constitute all of the carriers covering the United States and the District of Columbia. Attempts to include Puerto Rico's carrier in the survey were unsuccessful.

23 Two carriers reported that they even covered aerosolized pentamidine under the DME benefit. OTA did not follow up survey responses and so cannot confirm this.

for it. The other two had both instituted coverage only very recently; one had seen only a single claim so far, while the other carrier estimated that dobutamine already accounted for 10 percent of its drug claims under the DME benefit (365).

An interesting characteristic of current coverage of home-infused drugs is that because changes are made incrementally at the local level, and because two of the three drugs sanctioned by HCFA are for cancer therapy, patients with severe cancer have the greatest coverage. In the survey, all carriers covered morphine and some antineoplastics, and most also covered some other related drugs (e.g., other analgesics). Furthermore, where carriers covered additional categories of drugs, coverage was sometimes limited to patients already receiving other therapies. For example, four carriers covered adjunct therapies (e.g., hormonal therapies) for patients currently receiving home antineoplastic infusion; two carriers covered antibiotics only as adjuncts to antineoplastic therapy; and the two carriers that covered hydration did so only for patients already receiving infusion therapies (365).

The logic behind such coverage is that patients who are receiving home antineoplastic therapy should not be forced back into the hospital simply because of the need for additional related therapies. The result, however, is that under the present system, the sickest patients have the greatest coverage for HDIT, while the healthiest patients (e.g., needing only simple antibiotic therapy administered through a gravity drip) usually must remain hospitalized for the duration of their therapy.

Impact of Extending Coverage for HDIT

Extending Medicare coverage to include HDIT would increase the treatment options available to Medicare beneficiaries and the market possibilities for HDIT providers. It would also have more complex potential implications for Medicare expenditures, hospitals who provide inpatient infusion therapy, and the development of new health care technologies. These three issues are described below.

Implications for Medicare Expenditures

Whatever its advantages, an HDIT benefit would almost certainly raise Medicare expenditures in the first few years of its implementation. The major reason for this is that Medicare currently pays for hospital inpatient services on a per-case basis, according to a patient's diagnosis-related group (DRG). This payment system, as it currently stands, does not permit hospital payments to decrease in a given year even if more patients are discharged early to HDIT. In the longer run some offsetting inpatient savings might occur, as the hospital inpatient payment rate schedule is recalibrated to account for the lower hospital costs of serving these patients and hospital payments are reduced accordingly.

A 1987 study examined some of the potential effects on Medicare of extending coverage to home IV antibiotic therapy. This study included 150 home patients and 144 hospital patients who met the clinical criteria for home therapy but were treated in the hospital.[24] All home patients had to be able to self-infuse and had to be well enough to return home except for the need for continued therapy (e.g., no fever) (285).

The study found little difference in outcome between home and hospital therapy. Therapy was judged successful in 83 percent of home patients and 88 percent of hospital patients. Of patients for whom data from laboratory and other tests were available, results were nearly identical for the two settings (285).

To estimate potential Medicare expenditures, the study examined 1984 Medicare data on hospitalized patients in five DRGs that include an estimated two-thirds of the Medicare patients on long-term antibiotic therapy.[25] The researchers then simulated Medicare expenditures under various assumptions of the extent of home therapy and the ability of Medicare to adjust hospital inpatient rates.

In the base model, the researchers assumed that at equilibrium (i.e., several years after implementation of home IV antibiotic coverage), only 78 percent of patients would be hospitalized for their entire course of therapy. Of the remaining 22 percent, 12 percent would receive some hospitalization (e.g., for the initiation of therapy), and 10 percent would avoid

[24] Because of the difficulty id@@@ elderly home patients, some patients in the home group were under age 65.

[25] The DRGs examined were those for endocarditis, cellulitis, cellulitis with comorbidities, osteomyelitis, and osteomyelitis with wound debridement.

hospitalization entirely. The researchers also assumed that "treatment shifts" from oral to infused antibiotics would be minimal. Net savings (including savings from fewer physician visits in the home) were projected to be $16.9 million under baseline conditions. Changing baseline assumptions to reflect fewer home patients and fewer patients who could avoid hospitalization entirely reduced, but did not eliminate, the projected savings (285).

The results of this study imply that, for relatively independent Medicare patients on antibiotic therapy, Medicare expenditures would be equal or lower in the long run if infusion therapy were covered. To achieve this outcome, however, Medicare must first withstand greater expenditures in early years (until hospital payment rates can be readjusted to reflect the shorter inpatient stays). In addition, there must be no extra program costs incurred as a result of inequities among hospitals with differing abilities to discharge patients early (see below).

One factor not included in this study was dual coverage-i.e., Medicare beneficiaries who also have extensive private insurance benefits. Approximately 35 percent of elderly persons[26] are covered by private employer-based health insurance (242). Although the extent to which these Medicare beneficiaries are currently receiving privately covered HDIT is unknown, it may be substantial; one provider, for example, reports that 20 percent of its privately insured patients (who are 85 percent of their caseload) are also eligible for Medicare (83). Any Medicare coverage expansion for HDIT would probably result in some shift in spending from private payers to Medicare.

Implications for Hospitals

All else equal, implementing an HDIT benefit should result in reduced average lengths of hospital stay (ALOS) in the DRGs that include home-treated patients. The reductions would not apply equally to all people in those DRGs, however, nor would they be distributed equally among all hospitals.

Within any individual DRG, the advent of an HDIT benefit would result in some proportion of patients being discharged home after a short stay, while the remaining patients' stays are unchanged. Those patients in the first group will have lengths of stay lower than the average, generally leading to higher profits for the hospital. Patients in the second group, however, will often have longer lengths of stay than the average, and hospitals will lose money on most of them. Implementing an HDIT benefit thus would have a natural spiraling effect; as more patients were discharged early, ALOS in the DRG would decline, and the remaining sicker patients would come under ever-increasing pressure to leave the hospital early.

If there were no counterbalancing pressures or restrictions, the tendencies of the system could logically continue the spiral until even the sickest patients needing continuous care were discharged to home treatment. Counterbalancing pressures do exist, of course; they include Medicare payment restrictions for home care, physician disincentives to provide home care, home providers' unwillingness to accept severely ill patients, and hospitals' fear of legal liability for adverse outcomes in severely ill home patients.

Variability among hospitals' abilities to discharge patients to HDIT would prove to be a more serious and difficult problem to solve. Some hospitals—those with their own home infusion therapy companies, or with established arrangements with other providers of such care-are already well-positioned to take advantage of an HDIT benefit by discharging as many patients home as possible. Other hospitals do not yet have such arrangements but can make them reasonably quickly once a benefit is established. It is likely, however, that a third group of hospitals also exists: those that cannot discharge patients home because of the absence of an HDIT provider in the area they serve, or because the patients live in homes that are inadequate settings for such therapy. Furthermore, if these hospitals are located in very low-income or low-density areas, there may be little hope of home infusion providers being established in the future.

Where this is the case, hospitals will be forced to treat home-eligible patients as inpatients. The more successful other hospitals are at discharging patients home, the greater the financial losses of these hospitals in whom the ALOS remains unchanged through no fault of their own. The hospitals likely to suffer the most are those already facing fiscal

[26] Approximately 95 percent of the elderly (age 65 and over) are covered by Medicare.

difficulties: those that serve primarily rural or poor populations.[27]

For rural hospitals, swing beds may be a solution for some discharge difficulties related to HDIT. Medicare permits small rural hospitals to designate a proportion of their acute-care beds as "swing beds" and to receive reimbursement for either acute-or skilled-nursing-level care provided to patients in those beds. As of 1987, about 1,000 hospitals-roughly half of all eligible hospitals—had Medicare-certified swing beds (310). In these hospitals, patients needing only drug infusion therapy could be "discharged' to long-term care within the hospital itself and without changing the infusion-related services provided to the patient. This strategy might require some guidelines regarding at what point patients could be "discharged" from acute care, and it might require some changes in swing-bed payment rates, but it would probably relieve most rural hospitals from the most extreme effects of having no HDIT provider in their areas.

Urban hospitals serving large numbers of poor beneficiaries with inadequate homes do not have the swing-bed option. These hospitals will require additional payments (e.g., through the disproportionate share adjustment) or other alternative settings to discharge patients (e.g., nursing homes willing to accept infusion patients) if they are not to suffer undue losses.

Implications for Technological Change

Unless it is limited to a very few patients, Medicare coverage of HDIT would affect virtually every aspect of the home infusion industry. Medicare not only represents an enormous segment of the user market, but its benefit policies often serve as the boilerplate for other public and private insurance programs. In addition, Medicare's other policies and the special needs of its population may drive the market to respond to its own unique characteristics. Some of the possible areas for technological change are outlined below.

Development of Drugs and Drug Protocols

Most employer-based insurance policies pay for oral outpatient prescription drugs (19). At present, drug development favors oral drugs over other forms of administration because of their broad patient acceptance and large market. Developers go to some lengths to manufacture oral formulations; for example, despite the proven effectiveness of subcutaneous insulin, manufacturers continue to strive for an effective noninjectable form of the drug (301,303,304).

Medicare, however, does not presently cover most oral outpatient drugs. If Medicare does begin to pay for HDIT, it would add substantially to the already growing demand for parenteral drugs, while the oral drug market would remain the same. This disparity in demand by drug type would probably not cause developers to ignore oral formulations where these appear easily feasible, but it would make it less worthwhile to undertake additional research once a satisfactory parenteral form has been developed. One possible consequence of this incentive is to decrease investment in research aimed at oral drug delivery-the method that is ultimately least expensive for the health care system to deliver.

Medicare HDIT coverage would also probably fuel the existing trend toward longer, continuous or intermittent infusions rather than the short, intensive drug administration that is more suitable to the hospital. The greater potential market could lead not only to different protocols for newly developed parenteral drugs but to new uses of existing drugs (e.g., broader use of IV immune globulin) (see ch. 2).

Technological Change in Equipment and Supplies

Once a technology of drip bags and simple peripheral catheters, HDIT now can boast of an ever-expanding array of medical supplies and devices. Any Medicare coverage expansion is likely to add to the general incentives to develop new technologies for the HDIT market. In addition, it could stimulate technologies aimed more specifically at the special needs of the Medicare population, within the constraints of Medicare coverage policy.

Many Medicare patients, for example, may not be able to master or manipulate sophisticated infusion pumps. The need for simple, easily mastered equipment and supplies among this population is likely to direct device manufacturers' resources toward such areas as one-time, disposable infusion "pumps"; catheters pretreated with antibiotics to reduce infection; prepackaged and premeasured supplies that minimize handling needs; and other developments

27 In 1989, small rural hospitals (with fewer than 50 beds) and large urban hospitals with a disproportionate number Of poor patients had lower total hospital financial margins than any other hospital types (274).

that increase supply costs but might reduce the need for detailed patient training and professional assistance. Alternatively, if Medicare coverage incentives tended to encourage outpatient rather than home infusion, manufacturers would probably respond by developing more devices that could deliver a sophisticated variety of drugs in the home unaided but that might require intensive nursing attention as often as once a day.

Issues in Extending Coverage

Making Drug Coverage Decisions

As discussed in chapter 2, many drugs are being administered safely and effectively at home. However, some drugs are being used for which the evidence on effectiveness is ambiguous (e.g., dobutamine). Others are effective but may be dangerous in the home if not closely monitored and administered with proper precautions (e.g., many antineoplastics). Even within categories of relatively safe drugs there can be drugs that require especially strict precautions to be administered safely (e.g., the anti-infective amphotericin B), and drugs that are extremely costly for the benefit they confer to some patients (e.g., immune globulin).

Under an HDIT benefit, two basic questions regarding drug coverage decisionmaking would arise:

1. *Who should decide what drugs to cover?* And who should decide what limitations to place on the drugs that are covered?
2. *How should the drug coverage decisions be* made? How should the initial set of covered drugs be determined, and how should future drugs (or indications for existing drugs) be incorporated into those decisions?

Policy Under the Medicare Catastrophic Coverage Act

The MCCA (Public Law 100-360), passed in 1988, would have allowed Medicare to cover drugs that were safe and effective for IV administration in the home. The law required coverage for all antibiotics unless the Secretary of Health determined that a specific antibiotic could not be administered in the home setting in a safe and effective manner. Drugs which are not antibiotics were covered only if the *Secretary did determine* them to be safe and effective in the home. The drugs and accompanying diagnoses for which they were to be covered were published in the *Federal Register in* September 1989, just before the act was repealed. (This notice is reproduced in appendix C.)

Under the MCCA, Congress took on the responsibility for setting the categories of drugs to be covered, while delegating the responsibility for deciding on specific drugs and indications to HCFA. To produce the list of covered drugs and accompanying indications, HCFA obtained a list of drugs that were currently approved by the FDA for IV use. This list was then examined by individuals from HCFA, with advise from various professional groups and other sources, to determine the appropriateness of each particular drug for home infusion (368). Each drug was evaluated ad hoc and included or excluded on its own merits; no standardized process for review was used. Because HCFA has few physicians or pharmacists on staff, and received little assistance from FDA clinicians, the evaluators had little clinical expertise at their disposal.

This system produced a list that was plagued with seeming inconsistencies. For example, dilantin, an anticonvulsant agent used to control seizures, was included on the list of approved drugs despite the possibility of fatal adverse effects of this drug when given intravenously (216).[28] In contrast, erythromycin, an antibiotic with comparatively minor side effects, was not included.

The list of conditions for which approved drugs could be covered showed similar potential inconsistencies. HCFA omitted pulmonary infections from the list of approved conditions treatable with home antibiotics, for example, despite the fact that recurrent pulmonary infection related to underlying cystic fibrosis was one of the first indications for which home IV drugs were successfully administered (290).

The list of approved drugs and conditions was to be updated through a periodic review, with the timeframe for review unspecified in legislation. HCFA was prepared to update the list on an annual or semi-annual basis using a format that was not yet determined (368). FIs had very little discretion regarding drug coverage; their main function in this

[28] The potential for these adverse effects are so great that the manufacturer stresses that ' 'continuous monitoring of the electrocardiogram and blood pressure is essential" (216). Practically, this usually means administration of the drag in a hospital intensive care unit.

regard was to bring new drugs or indications to the attention of HCFA in order that they be incorporated to the next update.

Future Policies: Who Should Decide on Appropriate Drugs?

The final decision of which drugs are approved for home infusion could theoretically be made at any point on the regulatory spectrum, from Congress (through statute) to the individual physician (based on personal experience and opinion).

Congress could potentially not only establish categories of drugs to be covered but directly authorize which drugs and which conditions were appropriate for HDIT. Setting the drugs to be covered in statute eliminates ambiguity but makes updating the list extremely cumbersome. Such a level of legislative involvement in Medicare coverage decisions is unusual and, given the quantity of drugs to be considered and the rapidity of technological change in the pharmaceutical industry, probably undesirable. Congress could, however, set some general guidelines regarding the relative risks and benefits that are appropriate for Medicare to underwrite in the home.

HCFA has traditionally undertaken coverage tasks similar to those involved in HDIT. The list of procedures that are reimbursable if performed in an ambulatory surgical center, for example, is established in regulation and has been updated once since established in 1983 (see 53 F.R. 31468). Under the MCCA, however, HCFA's attempt to fill this role was troubled by a relatively short deadline and a lack of qualified clinical personnel. HCFA has little experience in drug evaluation and is not currently involved in any drug approval process. Requiring HCFA to approve drugs for home infusion use means that either HCFA must retain additional personnel who have detailed knowledge of the risks and benefits associated with drugs, or that HCFA must receive assistance from another agency with such expertise, such as the FDA.

Alternatively, the FDA itself could stipulate what constitutes safe and effective therapy in the home, using a similar process to its current approval process. In effect, this would amount to approval for labelling the drug for that use. The many drugs not specifically approved for home use thus could not be covered.

Fiscal intermediaries could decide what is proper infusion therapy for home use, making not only patient-specific decisions on appropriateness but establishing the general drug coverage categories as well. Many local medical carriers have already been involved in this activity to some extent through making drug decisions as part of the DME benefit, and some also may perform similar functions for their private insurance business.

FI-level drug coverage decisions permit relatively rapid updates to accommodate new therapies. This flexibility, however, would be purchased at the expense of some consistency; in contrast to a single HCFA list, the covered drugs and indications would probably differ somewhat among carriers depending on the expertise and practices of providers in their areas. Some of these differences might be justified; what can be safely provided at home may well often depend on provider experience with that drug. Other difference might be minimized with HCFA-mediated communication among carriers.

Finally, coverage could simply be made universally applicable for any drugs that *individual physician providers* prescribed for use in the home. This alternative is the most flexible and allows for rapid incorporation of new drugs and new procedures. On the other hand, individual provider responsibility for home infusion would probably result in a tremendous variation of practice which mayor may not be appropriate to the home setting. This level of decisionmaking also directly permits payment for experimental and untested drugs (or existing drugs being used in novel ways), without making any provisions that these experimental therapies be administered as part of an established protocol.

How Should Drug Coverage Decisions Be Made?

The ad hoc decisionmaking under the MCCA resulted in an irreproducible process that was heavily susceptible to criticism, and which HCFA might have been hard-pressed to defend in any legal challenge. To avoid this problem in the event of a new benefit, guidelines could be established (e.g., by Congress or HCFA) that would outline the approval process and the standard of evidence that a drug would have to meet to be approved.

Levels of Evidence-Achieving consistency in drug coverage decisionmaking requires adherence to an agreed-upon standard of evidence for establishing the safety and effectiveness of an infused drug in the

home. This standard would apply regardless of who actually made the drug-specific coverage decisions.

The most stringent standard would be that required by the FDA for approving the label of any drugs for marketing. In essence, this standard would be equivalent to saying that Medicare would pay only for drugs whose label specified that they were safe and effective when administration in that form, for that condition, in the home.

A second level of evidence could require that the drug be FDA-approved for the condition and that some data on its use at home be presented. This approach is entirely feasible, but it prohibits payment for "off-label" use-i.e., use of an FDA-approved drug for an indication not specifically approved by the FDA for the label. Off-label use is implicitly reimbursed in hospitalized patients, and a substantial proportion of the actual use of many drugs is for off-label use. A recent survey by the General Accounting Office, for example, found that nearly half of all cancer patients treated by oncologists receive, as part of their therapy, at least one drug whose label does not include that particular type of cancer (354). In the same survey, a number of oncologists reported having admitted patients to hospitals solely to have an off-label drug reimbursed (354). Thus, requiring this level of evidence would probably affect the actual therapies that physicians prescribed, and it would probably also result in fewer patients being treated at home than would otherwise be the case.

A third level of evidence could be to require that the drug be FDA-approved and that the particular indication be listed for that drug in common reference sources of drug information in order to be reimbursed. This standard would require less rigorous documentation in supporting the "possible" effectiveness of a drug and would probably have less effect on actual prescribing practices than more stringent standards. There might, however, be some pressure on the organizations that publish such reference books to make accommodations to manufacturers in order for a drug to qualify for Medicare reimbursement.

Finally, the level of evidence required could be one of a consensus of clinical experts, based on their personal judgment and knowledge of the literature. This is a formalized version of the practice of many local carriers, which use local clinical consultants to advise them regarding whether a particular procedure, for example, is generally considered safe and effective (i.e., nonexperimental) (359). This standard would have the least impact on actual prescribing practices but holds the greatest potential for leading to great variations in coverage decisions across geographic regions.

Applying Consistent Judgment—Whatever the stated standard of evidence to which decisionmakers would adhere, drug coverage decisions would inevitably require judgment on the part of those involved in the decision. For any given drug, they must decide whether the risk to patients of delivering a specific drug in the home is worth the potential benefit. The fact that a drug is risky does not itself eliminate the need to make this decision. Even drugs with unpleasant and sometimes severe side effects (e.g., most antineoplastics) are often considered worth using if the untreated disease is often fatal and there are few more benign alternatives.

The degree to which an evaluator considers the level of risk in a drug "acceptable' is likely to vary among individuals. Given this, one way to adhere to a consistent standard of tolerable risk would be to ensure that the same set of decisionmakers is responsible for each separate drug coverage decision. Within this group, decisionmakers could make a conscious attempt to apply individual and group judgments consistently. Thus, if HCFA were making the coverage decision, applying a consistent process might mean appointing an outside board of advisory experts to judge the relative risks and benefits of various drugs for various indications in the home. Alternatively, the advisory group might comprise FDA clinicians, or clinical and other employees of the Agency for Health Care Policy and Research. If FIs were to be the decisionmakers, the clinical advisors to the coverage decision might be advisory panels composed of local community physicians, pharmacists, and nurses.

Although clinical experience is not the only necessary skill to be represented in the group making the coverage decisions, it is a vital one. Deciding on an acceptable tolerance of risk requires clinical input, because it depends on a knowledge of the alternative treatments for that medical condition. Since the Medicare population is hugely elderly, knowledge of the drug's likely effects in the elderly population is also a valuable input that requires clinical experience.

HDIT Eligibility and Home Health Services

Many Medicare beneficiaries who might qualify medically for HDIT might also need assistive services-i.e., help with the infusion and any other needed care-if they were treated at home rather than in a health care setting. An estimated 40 percent of elderly persons need assistance with at least one basic activity of daily living (e.g., eating, dressing) (see ch. 3). Family caregivers would not necessarily be available or able to shoulder the burden of providing assistive health services; of the noninstitutionalized elderly, one-third live alone (386).

Because providing paid assistive health services increases the payer's costs of care for a patient on HDIT, the extent to which Medicare covers these services for HDIT beneficiaries would greatly affect Medicare expenditures. One way to affect the demand for assistive care by HDIT beneficiaries would be to institute payment mechanisms that discourage (or encourage) the provision of these services. Another, more direct alternative would be to design eligibility and coverage policies for the HDIT and the home health benefits to affect the use of such services (or the discharge of patients who would need such services). Some possible policies, and their potential implications, are described here.

Atone end of the spectrum, Medicare could cover HDIT only for patients who can demonstrate the capacity to administer the infusion without the assistance of a paid caregiver.[29] This alternative would restrict the benefit to a small number of patients who were alert and relatively healthy or who had family or fiends able to perform the administration. In the absence of more information about the relative costs of home and institutional care, this alternative offers the surest opportunity to achieve program cost savings. However, it restricts the ability of homebound patients, or those who might be able to avoid hospitalization altogether, to receive HDIT from a professional caregiver. It would also eliminate from eligibility for the benefit a large number of Medicare patients who would prefer to be treated at home but are unable to take responsibility for their own care.

At the opposite extreme, Medicare could extend eligibility for an HDIT benefit to any patient meeting some basic medical appropriateness criteria (e.g., the patient requires a parenteral drug and is medically stable). This criterion would permit the maximum number of beneficiaries to make use of the benefit. However, it would permit unlimited use of assistive home services, no matter how expensive, unless adjunct policies were also in place to limit these services.

Policies intermediate to these two extremes also exist, in which the covered benefits rather than the eligibility criteria would be restricted. These policies take the form of restricting both the assistive services covered under the HDIT benefit itself and the home health care benefits for which the patient might be concurrently eligible. For example, the HDIT benefit might include coverage of daily nursing to accommodate patients with needs for occasional nurse-administered infusions (e.g., up to 10 visits or 20 hours of home skilled nursing per week).

This alternative assumes that at some low level of professional assistance, home care is still less costly than institutional care. It might be particularly relevant if relatively low-cost outpatient care or institutional care in SNFs were not available, making hospital inpatient care the only real alternative to the home. However, this alternative also leaves open the possibility that program expenditures may actually increase under this alternative if the coverage is generous.

To avoid unwittingly paying for assistive services through the home health benefit in this example, HDIT patients could be disqualified from concurrent eligibility for that benefit. Thus, any infusion patient who also required unrelated skilled nursing care or other professional therapy or assistive services (e.g., physical therapy) could not be discharged home. This restriction would eliminate the possibility of paying for home care for patients who need very extensive services, but it raises the possibility that many patients might be discharged home and then rehospitalized (at Medicare's additional expense) if they developed a need for occasional additional care. It might also prevent many terminal or homebound patients, who currently qualify for home care services, from receiving their infusion at home as well. This policy might require that the home infusion and home health benefits be administered

[29] For example, a physician might be required to certify that the patient or family member could perform the infusion as a prerequisite for eligibility for the benefit.

by the same FI so that concurrent benefit eligibility could be detected.

Alternatively, the HDIT benefit could be very limited in its coverage of assistive services but beneficiaries could be permitted (if they qualified) to retain home health benefit eligibility at the same time. Under this scenario, coverage for concurrent home health benefits could itself be limited to restrain utilization of assistive services. For example, HDIT patients who were homebound could be covered for home health services up to a stated maximum limit (e.g., 50 percent of the average per-patient home health payment in that area). This alternative would allow for some assistance while providing an incentive for home providers to accept patients only if their anticipated assistive needs were few. However, it might also result in some underservice or rehospitalization of patients whose assistive needs were eventually greater than originally anticipated.

Chapter 7

PAYING FOR HOME DRUG INFUSION THERAPY UNDER MEDICARE

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Chapter 7

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 quali.tied 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 determiningg 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 fried 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 determiningg 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 freed-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 signifcant 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-l).

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 service[2] 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.

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

[3] Although 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-l—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 fusion 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-basedpayment, 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 l—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

[5] There 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 (O 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

[a]This 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.
[b]F_ee 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 AWPs 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 O 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 O 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: Cost per visit	Visits per time period	Length of episode	Potential impacts on quality of care
Rate per visit	Reduce	Reduce	increase	• Reduce length of visitor quality of staff
Comprehensive monthly rate	Reduce	Reduce	increase	• Reduce length of visit or quality of staff • Provide service too infrequently
Comprehensive per-episode rate	Reduce	Reduce	Reduce	• 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	• 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

[7] **Note 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 maybe 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 maybe 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 Fls. 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 coun-Q .

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

[8] 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. Alternatively, 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 predischarge 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, T^2, 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 another51 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 incidently 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 statutes[10] 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 maybe 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.

APPENDIXES

Appendix A
METHOD OF THE STUDY

History of the Project

The origins of this study lie in the passage of the Medicare Catastrophic Coverage Act of 1988 and its subsequent repeal in 1989. As part of a broad coverage expansion that would have extended Medicare coverage to outpatient prescription drugs, that act would have resulted in greater coverage of outpatient immunosuppressive drugs (now limited to coverage for only 1 year), and it would have established a home intravenous drug therapy benefit. With the repeal of that act, these two more specific coverage expansions once again became issues before Congress.

In April of 1990, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to revisit these two topics and the relevant coverage and payment issues they involve. The proposed assessment was approved by OTA's congressional Technology Assessment Board in June 1990 and begun the following month. The assessment was conducted in two parts leading to two separate reports, one on immunosuppressive drugs and one on home intravenous drugs and other drugs infused at home.

Conduct of the Home Drug Infusion Therapy (HDIT) Study

During the fall of 1990 and the frost 6 months of 1991, OTA staff reviewed the literature on HDIT and interviewed experts in home care, medicine, intravenous nursing, clinical pharmacy, and infusion equipment manufacturing. Project staff also met several times with individuals at the Health Care Financing Administration to learn from their experience with HDIT coverage after the Medicare Catastrophic Coverage Act, and with several private insurance company representatives regarding the experiences of private payers with HDIT.

In the course of the interviews and literature review, it became clear that objective and detailed information on many aspects of HDIT was incomplete or lacking entirely. To gain a more comprehensive understanding of the therapy and the industry that provides it, OTA made a number of site visits to providers. The organizations visited included a spectrum of hospital-, pharmacy-, home health agency-, and specialty-company-basecl HDIT programs. A list of these organizations appears at the end of this appendix. In addition, staff met with provider representatives at OTA and held extensive telephone interviews. OTA staff also met with individuals from organizations that include HDIT providers among their members.

OTA also requested detailed data on such aspects as provider structure and summary patient information from the providers contacted. Few providers were able to supply these data, lending insights into the information difficulties a Medicare policy might face.

Most major OTA studies have a panel of outside experts chosen to advise OTA staff on the study and ensure that all significant points of view are represented. This **study was originally intended to be performed in coordination with an ongoing study of drug research and development, with the same advisory panel. It transpired, however, that the two studies had little directly in common, and the advisory panel for the earlier study proved inappropriate for the existing study. Because of the short timeframe anticipated for this study, it also proved infeasible to appoint a separate advisory panel at the point for the current study.**

To ensure that sufficient expert advise was obtained and that all viewpoints were represented, OTA staff took great care to involve a variety of outside persons in the review of the draft material. A preliminary draft was sent to nearly 100 experts in the field, including HDIT providers, manufacturers, health professional and patient organizations, health care payers, researchers, and others with interest and knowledge in the area of HDIT for their review and comment. Fifteen representatives of the major organizations concerned with HDIT met at OTA for a public discussion of the draft on September 10, 1991 (see p. v of this report). The final draft, incorporating revisions based on reviewers' comments and discussion at the public meeting, was transmitted to the Technology Assessment Board in October 1991.

Contractors providing material to OTA for this study were:

Julia T. Ostrowsky, Chicago, IL, survey of Medicare Part B carriers regarding coverage of and payment for drugs used in infusion pumps under the durable medical equipment (DME) benefit, conducted February 1991.

Thomas W. Grannemann, Lexington, MA, "Incentives and Behavioral Responses to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program," prepared under contract to the Office of Technology Assessment, February 1991.

OTA Site Visits to HDIT Providers

Anne Arundel General Hospital Outpatient IV Therapy Services Program
Annapolis, MD
November 1990

Caremark
Columbia, MD
August 21, 1990

Handmaker Home Health Services, Inc.
Tucson, AZ
May 2, 1991

Infusion Care
Columbia, MD
August 2,1990

Jefferson County Department of Health
Birmingham, AL
November 1, 1990

HMSS, Inc..
Phoenix, AZ
May 3, 1991

New England Critical Care
Columbia, MD
August 21, 1990

Jefferson (Hospital) Home Infusion Service
Philadelphia, PA
September 20, 1990

University Medical Center Home Health Services, Inc.
Tucson, AZ
May 2, 1991

Vital Care, Inc.
Livingston, AL
November 2, 1990

Visiting Nurses Association of Washington
Washington, DC
February 4, 1991

Provider Visits to OTA

ABEL Health Management Services, Inc.
November 9, 1990

Arlington Cancer Center
April 25, 1991

Kimberly Quality Care
January 23, 1991

Appendix B
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This report was greatly aided by the assistance of many individuals who provided OTA staff with information and advice over the course of the study. OTA extends particular thanks to those persons who participated in the workshop discussion of the draft report (see inside front cover) and to the following individuals. (These individuals do not necessarily either agree or disagree with the findings and conclusions of this report. OTA assumes full responsibility for the report and the accuracy of its contents.)

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Honolulu, HI

Aetna-New Mexico/Oklahoma
Albuquerque, NM

Aetna-Oregon and Alaska
Portland, OR

Alabama Blue Shield
Birmingham, AL

Arkansas Blue Cross and Blue Shield
Little Rock, AR

Indiana Blue Shield
Indianapolis, IN

Blue Cross and Blue Shield of Arkansas-Louisiana
Baton Rouge, LA

Blue Cross and Blue Shield of Colorado
Denver, CO

Blue Cross and Blue Shield of Illinois
Chicago, IL

Blue Cross and Blue Shield of Kansas City
Kansas City, MO

Blue Cross and Blue Shield of Michigan
Detroit, MI

Blue Cross and Blue Shield of Montana
Helena, MT

Blue Cross and Blue Shield of North Dakota/Wyoming
Fargo, ND

Blue Shield of Rhode Island
Providence, RI

Blue Shield of Western New York
Binghamton, NY

California Blue Shield
San Francisco, CA

Empire Blue Shield
New York, NY

Equicor-Maho
Boise, ID

Equicor North Carolina
Greensboro, NC

Equicor Tennessee
Nashville, TN

Florida Blue Shield
Jacksonville, FL

General American L*ife Insurance Co.*
St. Louis, MO

Group Health Incorporated
New York, NY

Iowa Blue Shield
Des Moines, IA

Kansas/Nebraska Blue Shield
Topeka, KS

Kentucky Blue Shield
Lexington, KY

King County Medical Blue Shield
Seattle, WA

Maryland Blue Cross and Blue Shield
Timonium, MD

Massachusetts Blue Cross and Blue Shield
Boston, MA

Minnesota Blue Shield
St. Paul, MN

Nationwide Insurance Co.
Columbus, OH

Pennsylvania Blue Shield—New Jersey
Lawrenceville, NJ

South Carolina Blue Shield
Columbia, SC

Texas Blue Shield
Dallas, TX

Transamerica Occidental Life Insurance Co.
Los Angeles, CA

Travelers of Connecticut
Hartford, CT

Travelers of Minnesota
Bloomington, MN

Travelers of Mississippi
Jackson, MS

Travelers of Virginia
Richmond, VA

Utah Blue Shield
Salt Lake City, UT

Wisconsin Physicians' Service
Madison, WI

HOME INTRAVENOUS DRUG THERAPY: PROPOSED REGULATIONS UNDER THE MEDICARE CATASTROPHIC COVERAGE ACT

The Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360) included a new Medicare benefit that would have covered home intravenous drug therapy. The act, and the benefit, were repealed the following year. Shortly before the repeal, however, the Health Care Financing Administration (HCFA) had published proposed regulations to implement this new benefit. Although the proposed rules were never made final, they generated considerable comment from the industry, and they represent a potential baseline against which any future related policies can be compared.

The remainder of this appendix presents exerpts from the ***Federal Register*** that relate to coverage and payment for home intravenous drug therapy. Exerpts are ordered as follows:

- list of covered home intravenous drugs (54 F.R. 37239, Sept. 7, 1989);
- payment for covered outpatient drugs (54 F.R. 37208, Sept. 7, 1989);
- coverage of home intravenous drug therapy services (54 F.R. 37422, Sept. 8, 1989);
- payment for home intravenous drug therapy services (54 F.R. 46938, NOV. 8, 1989); and
- conditions of participation for home intravenous drug therapy providers (54 F.R. 37220, Sept. 7, 1989).

Specific relevant sections and paragraphs are exerpted verbatim (including abbreviations), but sections omitted are not explicitly indicated. Headings and some sections have been reformatted for publication purposes in this report.

List of Covered Home IV Drugs (54 F.R. 37239)

This notice sets forth a list of intravenous drugs that we [HCFA] propose to cover on the basis that they can be safely and effectively administered in the home. The notice would implement section 1861(t)(4) of the Social Security Act as added by section 202(a) of the Medicare Catastrophic Coverage act of 1988.

Home IV Coverage

Section 202(a) of Pub. L. [Public Law] 100-360 amended sections 1861(s)(2)(J) and (t) of the Act to provide general coverage for outpatient prescription drugs under Part B and to authorize Part B coverage of home IV drugs. In addition, section 203 of Pub. L. 100-360 added sections 1861(jj), 1834(d) and 1835(a)(2)(G) to the Act and amended other related sections to authorize coverage of home IV therapy services. For purposes of this new home IV benefit, under new section 1861(t)(4)(B) of the Act, we are required to publish, by January 1, 1990 and periodically thereafter, a list of covered home IV drugs, and their indications, that can be safely and effectively administered in the home.

It is this list of drugs that we are addressing in this proposed notice. Proposed rules setting forth regulations to implement the various other provisions of Pub. L. 100-360 dealing with the outpatient prescription and home IV drug benefits will be published in separate documents as follows:

- Overall coverage of outpatient prescription drugs (including drugs used in immunusuppressive therapy and home IV drugs).
- Payment methodology for covered outpatient prescription drugs (which will apply also to covered home IV drugs).
- Coverage of home IV drug therapy services.
- Conditions of participation for home TV drug therapy providers.
- Fee schedule for home IV drug therapy services.
- Deductible and coinsurance amounts and the Part B cap on out-of-pocket expenses.
- Participating pharmacies.
- Drug bill processors.
- Coverage of catastrophic Part B expenses, outpatient drug expenses, and respite care benefits for beneficiaries enrolled in pre-pay health plans, such as health maintenance organizations.

The statute provides specific definitions of "covered outpatient prescription drugs" and of what constitutes ''covered home IV drugs. In order to be a covered home IV drug, the drug must first qualify as a covered outpatient prescription drug as described below.

Section 202(a) of Pub. L. 100-360 amended sections 1861(s)(2)(J) and (t) of the Act by establishing the following definition of a "covered outpatient drug," which includes drugs, biological products, and insulin.

Drugs-A drug that may be dispensed only upon prescription and that meets one of the following requirements:

- The drug is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the FFDCA [Federal Food, Drug, and Cosmetic Act], or approved under section 505(j) of the FFDCA.

. The drug was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1%2 (October 10, 1%2) or it is identical, similar or related to such a drug, as defined by 21 CFR 310.6(b)(l). Nevertheless, such a drug will not be covered if the Secretary has made a final determination that it is a "new drug' and has not been approved under sections 505 or 507 of the FFDCA, or if it is subject to certain actions brought by the Secretary to enforce provisions of sections 502(f), or 505(a) of the FFDCA (21 U.S.C. 352(f), or 355(a)).

. The drug is described in section 107(c)(3) of the Drug Amendments of 1962 and is one for which the Secretary has determined there is compelling justification for its medical need, or it is identical, similar, or related to such a drug. Also, the drug must be one for which the Secretary has not issued a notice to withdraw approval for marketing, because the Secretary has determined that the drug is less than effective for all conditions of use represented, recommended, or suggested on its labeling. These are the ''DESI' [Drug Efficacy Study Implementation] drugs.

Biological **products—A** biological product is considered a "covered outpatient drug" if it is one that may be dispensed only upon prescription, is licensed under section 351 of the PHS [Public Health Service] Act (42 U.S.C. 262), and is produced at an establishment licensed under that Act to produce that product.

Insulin—Insulin is covered if it is certified under section 506 of the FFDCA (21 U.S.C. 356) for the strength, quality, and purity necessary to ensure adequate safety and efficacy of use. In accordance with section 1861(t)(2)(C) of the Act, as amended by Pub. L. 100-360, insulin would be considered a "covered outpatient drug" whether or not it is dispensed under a prescription.

In addition, section 202(a)(2)(C) of Pub. L. 100-360 added sections 1861(t)(4)(A) and (B) to the Act to define "covered home IV drugs" as covered outpatient drugs that are intravenously administered to individuals in places of residence that are used as the individuals' homes. The definition includes:

- Antibiotic drugs unless the Secretary has determined, for a specific drug or for the indication for which it is applied, that the drug cannot generally be administered safely and effectively in a home setting; and
- Drugs that are not antibiotics, but only if the Secretary has determined that for a specific drug and the indications for which the drug is being applied that it can generally be administered safely and effectively in a home setting.

Process Followed in Compiling the Drug List

Description of **the** Process-As noted above, section 202(a)(2)(C) of Pub.L. 100-360 added section 1861(t)(4)(B) to the Act to require us to develop a list of covered home IV drugs by January 1, 1990. These drugs must meet definitions of a "covered outpatient drug" set forth in new sections 18 61(t)(2) and (2) or the Act and of a "covered home IV drug" set forth in new section 1861(t)(4)(A) of the Act.

Our task with respect to putting together a proposed list of covered home IV drugs has been twofold. First, we had to compile a list of IV drugs (both antibiotics and non-antibiotics) and their indications. Second, in accordance with section 1861(t)(4) of the Act, we had to identify from that list those IV drugs that are safe and effective for use in the home. In accordance with section 1861(t)(4)(A)(ii) of the Act, our rules for including antibiotics and non-antibiotics differed. We obtained information about IV drugs based on the following categories:

. Antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home.

. Non-antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home. We separated this category into the following groups:
—Anti-infectives (other than antibiotics);
—Hydration therapy;
—Pain management drugs;
—Antineoplastic drugs; and
-Other drugs.

In determining which drugs may be administered intravenously, we obtained the following lists from the FDA:

- **All IV drugs** that are **currently approved by the FDA for marketing,**
- **DESI drugs, [and]**
- **"Compliance Report for DESI-2," also referred to** as the "B List" of unapproved drugs that are currently marketed.

The drugs that we considered for our proposed list had to meet the statutory definition of "covered outpatient drug" and can be found on one of these FDA generated lists. Before we reviewed a specific drug for possible inclusion as a "covered home IV drug," the drug had to meet this initial requirement, as set forth in section 1861(t) of the Act.

In listing the drugs, we decided to place together in one list all those drugs, both antibiotics and non-antibiotics, that we initially propose as being covered. We believe setting forth a comprehensive list of covered drugs for

purposes of rulemaking will make it easier for the public to direct their comments appropriately to a specifically named drug or indication, as opposed to our soliciting comments on those antibiotics and their indications that we propose not to cover. As discussed below, we encountered special problems with unlabeled indications for antibiotics in this regard. Therefore, [Table C-1] to this notice contains a list of drugs and indications that we propose to cover. [Table C-2] contains a list of antibiotics and indications that we propose not to cover.

We want to emphasize that we do not have the discretion under the home IV drug benefit to pay for a drug or an indication that is not on the final list. Section 1861(t)(4)(A) of the Act, as added be section 202(a) of Pub. L. 100-360, limits coverage of home IV drugs to those drugs that the Secretary has determined are safe and effective for use in the home. Any drug or indication not addressed on the final list to be published after we consider and evaluate public comments on the attached proposed list, or any drug or indication not included in a subsequent update, would not meet this requirement and payment would not be made for that drug or indication.

To obtain advice in determining whether an IV drug should be included in our proposed list of IV drugs as being safe and effective for use in the home, we contacted the following organizations:

. The U.S. Pharmacopoeia (UPS).
. The American Society of Hospital Pharmacists (ASHP).
. The American Medical Association (AMA).
• Various home IV providers (recognized in he field of home IV therapy).
• The pharmaceutical Manufacturers Association.
• Various drug manufacturers.

We requested that these sources submit a list of IV drugs that, in their opinion, could generally be safely and effectively administered in the home, and, in addition, any other information they thought pertinent. Although all of the organizations we contacted did not respond with recommendations about drugs suitable for home use, we did receive specific recommendations based on reviews by advisory panels, medical and clinical evidence to support inclusion of certain drugs, lists of IV drugs that are currently being administered in the home setting, and recommendations for exclusions.

In addition, we contacted the publishers of the following compendia:

- United States Pharmacopoeia Dispensing Information, Volume 1 (Drug Information for the Health Care Professional)(USP DI);
- American Medical Association's Drug Evaluations (AMADE); and
. American Hospital Formulary Service Drug Information (AHFS DI).

Based on the information we received from all of these sources, we constructed an initial list of IV drugs that we considered for inclusion on the proposed list as being safe and effective for home use. (At this point, the list included certain antineoplastic drugs but did not include 12 of the antibiotic drugs that were included on the master list of IV drugs submitted to us by the FDA. For reasons discussed below, neither of these groups of drugs is included in [table C-l].) We then obtained form the FDA the labeled indications for these drugs.

For the purpose of determining unlabeled uses of approved drugs, we relied on the information provided by the three compendia and the suggestions of the various home IV providers.

Having put together the list of IV drugs and indications, we then submitted it to health care professionals recommended to us by the Intravenous Nurses Society and the AMA [American Medical Association]. We requested that these individuals examine the list from a clinical perspective and we received several clinical recommendations.

As noted earlier, our rules for including antibiotic and non-antibiotic drugs on the proposed list have differed. The law requires the Secretary to coverall antibiotic drugs unless the Secretary makes the determination that a specific antibiotic cannot generally be administered safely and effectively in the home. The list of IV drugs we initially obtained from the FDA included identification of all IV antibiotic drugs that are currently available on the market. Of those antibiotic drugs, there were 12 antibiotics that we are proposing as not generally being safe and effective for use in the home.

It is our understanding that the following factors may prevent these 12 drugs that we propose for exclusion from being safe or effective when administered in the home setting:

. Potential serious or life-threatening side effects;
• Stringent monitoring requirements that could not effectively be performed in the home setting; and
. Stability limitations.

We list these 12 antibiotics below and specifically solicit comments and information about these drugs and their indications that might be relevant to a final determination about their suitability for use in the home. The drugs are:

1. Chloramphenicol sodium succinate
2. Colistimethate sodium
3. Doxycycline hyclate
4. Erythromycin gluceptate
5. Erythromycin lactobionate

Table C-I—Proposed List of Covered Home IV Drugs and Indications

Approved drug/Approved conditions
Antibiotics
Amdinocillin
Urinary tract infections, bacterial
Amikacin sulfate
Bone and joint infections
Endocarditis, bacteria
Genitourinary tract infections
Skin and soft-tissue infection
Urinary tract infections, bacterial
Ampicillin sodium
Arthritis, gonococcal
Bone and joint infections
Endocarditis, bacterial
Entercolitis, "Shigella"
Genitourinary tract infections
Gonorrhea
"Hemophilus" infections
Listeriosis
Paratyphoid fever
Skin and soft-tissue infections
Urethritis, gonococcal
Ampicillin sodium and sulbactam sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract injections
Skin and skin structure infections
Azlocillin sodium
Bone and joint infections
Endocarditis, bacterial
Skin and skin structure infections
Urinary tract infections, bacterial
Aztreonam
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Carbenicillin Disodium
Genitourinary tract infections
Skin and soft-tissue infections
Urinary tract infections, bacterial
Cafamandole nafate
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cefonicid sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cefoperazone sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Ceforanide
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cefotaxime sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cefotetan disodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cefoxitin sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Ceftazidime
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Ceftizoxime sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Ceftriaxone sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Lyme Disease, joint and Central Nervous System (CNS)
Cefuroxime sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Gonorrhea
Cephalothin sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and soft tissue infections
Urinary tract infections, bacterial
Cephapirin sodium
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial
Cephradine
Bone and joint infections
Endocarditis, bacterial
Genitourinary tract infections
Skin and skin structure infections
Urinary tract infections, bacterial

Table C-l—Proposed List of Covered Home IV Drugs and Indications-Continued

Approved drug/Approved renditions	Approved drug/Approved conditions
Clindarnycin phosphate	Genitourinary tract infections
Bone and joint infections	Skin and skin structure infections
Genitourinary tract infections	Urinary tract infections, bacterial
Skin and soft tissue infections	Urethritis, gonococcal
Gentamicin sulfate	Ticarcillin disodium
Bone and joint infections	Bone and joint infections
Endocarditis, bacterial	Endocarditis, bacterial
Genitourinary tract infections	Genitourinary tract infections
Skin and skin structure infections	Skin and soft tissue infections
Urinary tract infections, bacterial	Urinary tract infections, bacterial
Listeriosis	Ticarcillin disodium and
Imipenem and Cilastatin Sodium	clavulanate potassium
Bone and joint infections	Bone and joint infections
Genitourinary tract infections	Endocarditis, bacterial
Skin and skin structure infections	Genitourinary tract infections
Urinary tract infections, bacterial	Skin and skin structure infections
Methicilin sodium	Urinary tract infections, bacterial
Endocarditis, bacterial	Tobramycin sulfate
Skin and soft tissue infections	Bone and joint infections
Mezlocillin sodium	Endocarditis, bacterial
Bone and joint infections	Genitourinary tract infections
Endocarditis, bacterial	Skin and skin structure infections
Genitourinary tract infections	Urinary tract infections, bacterial
Skin and skin structure infections	Listenosis
Urinary tract infections, bacterial	Vancomycin hydrochloride
Miconazole	Bone and joint infections
Candidiasis, disseminated	Endocarditis, bacterial
Candidiasis, mucocutaneous, chronic	
Petriellidiosis	**Non-antibiotic drugs**
Urinary bladder infections, fungal	*Anti-in fectives (other than antibiotics)*
Nafcillin sodium	Acyclovir sodium
Endocarditis, bacterial	Herpes zoster
Skin and soft tissue infections	Herpes simplex
Netilmicin Sulfate	Pentamidine isethionate
Bone and joint infections	Pneumonia, "Pneumocystis carinii"
Endocarditis, bacterial	Leishmaniasis, visceral
Genitourinary tract infections	Tryponosomiasis, African
Skin and skin structure infections	Sulfamethoxazole and trimethoprim
Urinary tract infections, bacterial	Bone and joint infections
Oxacillin sodium	Chancroid
Endocarditis, bacterial	Chlamydial infections
Skin and soft tissue infections	Enterocolitis "Shigella"
Penicillin G Potassium	Genitourinary tract infections
Arthritis, gonococcal	Gonorrhea
Diphtheria, prophylaxis	"Hemophils" infections
Endocarditis, bacterial	Lymphogranuloma venereum
Genitourinary tract infections	Paratyphoid fever
Gingivostornatitis, necrotizing ulcerative	Pneumonia, "Pneumocystis carinii"
Listeriosis	Rheumatic fever
Lyme disease, joint and CNS	Urinary tract infections, bacterial
Syphilis	
Penicillin G sodium	*Hydration Therapy*
Arthritis, gonococcal	Intravenous solutions
Diphtheria prophylaxis	1. Dextrose in water solutions
Endocarditis, bacterial	2. Sodium chloride solutions
Genitourinary tract infections	3. Dextrose/sodium chloride solutions
Gingivostomatitis, necrotizing ulcerative	4. Premixed potassium chloride solutions up to concentrations of 40 mEq/Lip
Listenosis	
Lyme disease, joint and CNS	The following limitations apply for all of the above solutions:
Syphilis	a concentration of dextrose in any solution is not to exceed 10%.
Piperacillin sodium	b. concentration of sodium chioride in any solution is not to exceed 0.9°/0.
Bone and joint infections	
Endocarditis, bacterial	

(continued on next page)

Table C-l—Proposed List of Covered Home IV Drugs and Indications-Continued

Approved drug/Approved conditions
5. premixed electrolyte solutions, containing any combination of the following electrolytes in their various salt forms, which are not intended for parenteral nutrition:
Sodium
Potassium
Calcium
Magnesium
Chloride
Phosphate
The caloric content of these solutions is limited to 340 calories.
Electrolytes
1. Calcium chloride
2. Calcium glumnate
3. Calcium glucepate
4. Magnesium chloride
5. Magnesium sulfate
6. Potassium acetate
7. Potassium chloride
8. Potassium phosphate
9. Sodium acetate
10. Sodium bicarbonate
11. Sodium chloride
12. Sodium phosphate
The indications for drugs in this category are less specific than for other drugs. After referring to various clinical tests, we have determined that water depletion, and combined water and electrolyte depletion, can be the result of many disease and non-disease states, including but not limited to the following:
Extrarenal losses
1. Gastrointestinal (vomiting, diarrhea, ostomy drainage)
2. Skin losses (sweating, burns)
3. Lung losses (bronchorrhea)
Renal losses
1. Renal disease (chronic renal failure, diuretic phase of acute renal failure)
2. Diuretic excess
3. Osmotic diuresis (diabetic glycosuria)
4. Mineralcorticoid deficiency (Addison' s disease, hypoaldosteronism)
There may be other instances when a patient needs hydration therapy. Patients taking antineoplastic drugs must often be hydrated to increase urine output to insure the timely excretion of the drug because of its toxic side effects.
Pain Management Drugs
Indication: for treatment of chronic intractable pain.
Butorphanol tartrate
Hydromorphone hydrochloride
Meperidine hydrochloride
Morphine sulfate
Other
Aminophylline
Asthma, bronchila
Bumetanide
Edema
Cimetidine hydrochloride
Adenoma, multiple endocrine
Bleeding, upper gastrointestinal
Hypersecretory conditions, gastric
Mastocytosis, systeic
Pancreatic insufficiency
Reflux, gastroesophagel
Stress-related mucosal damage
Ulcer, duodenal
Ulcer, gastric
Zollinger-Ellison syndrome
Deferoxamine mesylate
Toxicity, iron chronic
Toxicity, aluminum
Dexamethasone sodium phosphate
Adrenocortical insufficiency, chronic primary (Addison's)
Adrenomrtical insufficiency, secondary
Adronogenital syndrome (adrenal hyperplasia, congenital)
Anemia, hemolytic, acquired (autoimmune)
Anemia, hypoplastic, congenital (erythroid)
Anemia, red blood cell (erythroblastopenia)
Arthritis, psoriatic
Arthritis, rheumatoid
Bowel disease, inflammatory, including colitis, ulcerative
Bronchitis, asthmatic, acute or chronic
Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
Carcinoma, breast
Carcinoma, prostatic
Connective tissue disease, mixed
Dermatitis, exfoliative
Dermitis herpetiformis bullous
Dermatitis, seborrheic, severe
Dermatomyositis, systemic
Dermatoses, inflammatory, severe (Stevens-Johnson syndrome)
Fever, due to malignancy
Gouty arthritis, acute
Hemolysis
Hypercalcemia associated with neoplasms (or sarcoidosis)
Increased cranial pressure due to malignancy
Leukemia acute or chronic
Lupus erythematosus, systemic
Lymphomas, Hodgkins, or non-Hodgkins
Multiple myelome
Mycosis fungoides
Nausea and vomiting, cancer-chemotherapy induced
Penphigoid
Pemphigus
Polychondritis, relapsing
Polymyalgia, rheumatic
Polyps, nasal
Pulmonary disease, chronic obstructive (not controlled with theophylline and beta-adrenergic agonists)
Reiter's disease
Rheumatic fever
Rhinitis, allergic, perennial, or seasonal, severe
Thrombocytopenia secondary in adults
Thrombocytopenia purpura, idiopathic, in adults
Trichinosis
Diphenhydramine hydrochloride
Nausea and vomiting
Famoticine
Adenoma, multiple endocrine
Bleeding, upper gastrointestinal
Hypersecretory conditions, gastric
Mastocytosis, systemic
Pancreatic insufficiency
Reflux, gastroesophageal
Stress-related mucosal damage
Ulcer, duodenal
Ulcer, gastric
Zollinger-Ellison syndrome

Table C-l—Proposed List of Covered Home IV Drugs and indications-Continued

Approved drug/Approved conditions
Furosemide
Edema
Heparin Calcium
Heparin sodium
Thromboembolism
Hydrocortisone sodium phosphate
Hydrocortisone sodium succinate
Adrenocortical insufficiency, chronic primary (Addison's)
Adrenocortical insufficiency, secondary
Adrenogenital syndrome (adrenal hyperplasia congenital)
Anemia, hemolytic, acquired (autoimmune)
Anemia, hypoplastic, congenital (erythroid)
Anemia, red blood cell (erythroblastopenia)
Arthritis, psoriatic
Arthritis, rhematoid
Bowel disease, inflammatory, including colitis, ulcerative
Bronchitis, asthmatic, acute or chronic
Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
Carcinoma, breast
Carcinoma, prostatic
Connective tissue disease, mixed
Dermatitis, exfoliative
Dermatitis, herpetiformus, bullouss
Dermatitis, seborrheic, severe
Dermatomyositis, systemic
Dermatoses, inflammatory, severe
Enteritis, regional (Crohn's disease)
Erythema multiform, severe
Fever, due to malignancy
Gouty arthritis, acute
Hemolysis
Hypercalcemia associated with neoplasms (or sarcoidosis)
Increased cranial pressure, due to malignancy
Leukemia, acute or chronic
Lupus erythematosus, systemic
Lymphomas, Hodgkin's or non-Hodgkin's
Multiple myeloma
Mycosis fungoides
Nausea and vomiting, cancer chemotherapy induced
Pemphigoid
Penphigus
Polychondritis, relapsing
Polymyalgia, rheumatic
Polyps, nasal
Pulmonary disease, chronic obstructive
Reiter's disease
Rheumatic fever
Rhinitis, allergic, perennial or seasonal, severe
Thrombocytopena, secondary, in adults
Thrombocytopenia purpura, idiopathic, in adults
Trichinosis
Iron dextran
Iron deficiency anemia
Leucovorin calcium
Methotresate toxicity (antidote to folic acid antagonist)
Mannitol
Premeditation, cancer chemotherapy
Methylprednisolone sodium succinate
Adrenocortical insufficiency, chronic primary (Addison's)
Adrenocortical insufficiency, secondary
Adrenogenital syndrome (adrenal hyperplasia, congenital)
Anemia, hemolytic, acquired (autoimmune)
Anemia, hypoplastic, congenital (erythroid)
Anemia, red blood cell (erythroblastopenia)
Arthritis, psoriatic
Arthritis, rhematoid
Bowel disease, inflammatory, including colitis, ulcerative
Bronchitis, asthmatic, acute or chronic
Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
Carcinoma, breast
Carcinoma, prostatic
Connective tissue disease, mixed
Dermatitis, exfoliative
Dermatitis, herpetiformus, bullouss
Dermatitis, seborrheic, severe
Dermatomyositis, systemic
Dermatoses, inflammatory, severe
Enteritis, regional (Crohn's disease)
Erythema multiform, severe
Fever, due to malignancy
Gouty arthritis, acute
Hemolysis
Hepatitis, chronic active
Hepatitis, nonalcoholic, in women
Hypercalcemia associated with neoplasms (or sarcoidosis)
Increased cranial pressure, due to malignancy
Leukemia, acute or chronic
Lupus erythematosus, systemic
Lymphomas, Hodgkin's or non-Hodgkin's
Multiple myeloma
Mycosis fungoides
Necrosis, hepatic, subacute
Pemphigoid
Penphigus
Polychondritis, relapsing
Polymyalgia, rheumatic
Polyps, nasal
Pulmonary disease, chronic obstructive
Reiter's disease
Rheumatic fever
Rhinitis, allergic, perennial or seasonal, severe
Thrombocytopenia secondary, in adults
Thrombocytopenia purpura, idiopathic, in adults
Trichinosis
Metoclopramide
Gastroparesis
Nausea and vomiting, cancer chemotherapy induced
Phenytoin Sodium
Epilepsy
Prochlorperazine Edisylate
Nausea and vomiting
Ranitidine hydrochloride
Adenoma, multiple endocrine
Bleeding, upper gastrointestinal
Hypersecretory conditions, gastric
Mastocytosis, systemic
Pancreatic insufficiency
Reflux, gastroesophageal
Stress-related mucosal damage
Ulcer, duodenal
Ulcer, gastric
Zollinger-Ellison syndrome
Biologlcals and Indications
Immune globulin
Immunodeficiency syndrome
Thrombocytopenic purpur~ idiopathic
Alpha-proteinase inhibitor, human
Emphysema panacinar, due to alpha-antitrypsin deficiency

Table C-2—Proposed List of Non-Covered Home IV Antibiotic Drugs and Indications

Antibiotic Drugs Not Proposed for Coverage	Conditions
Chloramphenicol sodium succinate	Biliary tract infections
Colistimethate sodium	Central nervous system infections
Doxycycline hyclate	Intra-abdominal infections
Erythromycin glucepate	Respiratory tract infections
Erythromycin lactobionate	Septicemia
Kanamycin sulfate	
Lincomycin hydrochloride	
Minocycline hydrochloride	
Moxalactum disodium	
Oxytetracycline hydrochloride	
Polymyxin B sulfate	
Tetracycline hydrochloride	

6. Kanamycin sulfate
7. Lincomycin hydrochloride
8. Minocycline hydrochloride
9. Moxalactum disodium
10. Oxytetracycline hydrochloride
11. Polymyxin B sulfate
12. Tetracycline hydrochloride.

In addition, we want to note that, in our administrative process of assembling the list of antibiotic drugs (covered and noncovered), we believe that we have addressed all antibiotic drugs currently on the market. However, the introduction of new drugs into the marketplace is an ongoing occurrence. In addition, it is not inconceivable that in our process, we may have inadvertently missed an antibiotic drug. Therefore, we also invite public comment concerning antibiotics that do not appear in either appendix.

For non-antibiotic drugs, the Secretary has to make a determination that a drug can generally be safely and effectively administered in the home. Therefore, before and IV drug could be placed on Appendix I, we had to develop evidence from which that determination could be made. We derived this list based on consultations with the USP DI and the AHFS DI, providers of home IV therapy, and a review of available medical and scientific information.

With respect to the antineoplastic drug subcategory, we initially considered the following drugs for inclusion on the list:

1. Bleomycin sulfate
2. Cyclophosphamide
3. Cytarabine
4. Daunorubicin hydrochloride
5. Diethylstilbestrol diphosphate
6. Doxorubicin hydrochloride
7. Etoposide
8. Fluorouracil
9. Methotrexate sodium
10. Mitomycin
11. Mitoxantrone hydrochloride
12. Streptozocin
13. Vinblastine sulfate
14. Vincristine sulfate.

Concerns were raised throughout the process of developing and clearing the list about the general safety of this group of drugs when administered intravenously in the home setting. A review of the drug labels revealed that of the 14 drugs in this category, 12 of them had warnings that specified that the drug should be administered by or under the supervision of a qualified physician who is experienced in cancer therapy. In addition, several drugs had additional warnings that patients should have access to or be treated in a facility with laboratory and supportive resources sufficient to monitor drug tolerance. We also reviewed the National Institutes of Health (NH) recommended guidelines for the "Handling of Parenteral Antineoplastic Drugs" prepared in collaboration with oncologists, the clinical center pharmacy (within NIH), oncology nurses, and National Cancer Institute staff. With these factors to consider, and mindful also of the extensive safety requirements these factors could necessitate in the conditions of participation for home IV drug providers, we concluded that we are not able to propose, at this time, that these drugs could be safely and effectively administered intravenously in the home. In order to be consistent with the approved FDA labeling, we made the decision to remove these drugs from [table C-l]. Because of the concern about whether antineoplastics are safe for use in the home, we have decided to seek further advice form the Public Health Service on this matter. Coverage of antineoplastic drugs under the home IV therapy benefit will accordingly be deferred pending receipt of such advice.

Use of Compendia—We selected the three compendia listed above as reliable sources for some of the advice and information we needed based on the recommendations contained in the Conference Report accompanying Pub. L. 100-360 (H.R. Report No. 661, 100th Congress, 2d Session 192 (1988)). In the report, the three compendia are suggested for consideration as references for a related purpose under the new drug benefit, that is, for purposes of the establishment of standards for covered outpatient prescription drugs, as required under the new section 1834(c)(5)(B) of the Act (as added by section 202(b)(4) of Pub. L. 100-360). Since Congress recognized these compendia as authoritative for one purpose under the new drug benefit, we believe it is appropriate to rely on them for a related similar purpose under that benefit.

In addition, the USP DI is sponsored by the USP, and organization that includes members of schools of medicine and pharmacy, State medical and pharmacy associations, national medicine and pharmacy associations. Its

listing of drugs includes virtually all drugs approved in the United States. The USP DI staff prepare monographs after a literature search and review of FDA approved labeling. (A monograph is an essay or treatise on the available data for a specified drug.) These monographs are reviewed by over 300 additional experts, plus many schools, associations, pharmaceutical companies, and government agencies. They are again reviewed by advisory panels until a consensus is developed. Proposed monographs are then published in the USP DI Review for general public comment before being published in the USP DI. The USP DI is republished annually with six supplements per year and contains individual monographs, most information from the FDA-approved label, and unlabeled uses of approved drugs.

The AHFS DI is sponsored by the American Society of Hospital Pharmacists, which represents 22,000 pharmacists. AHFS DI staff prepare monographs after a literature search and review of FDA labeling. These monographs are reviewed by over 300 specialists at the doctoral level, including physicians, pharmacologists, and biochemists selected form among experts in drug therapy. This review process continues until a consensus is developed. The AHFS DI includes individual drug monographs with some general category statements, full FDA label disclosure, and unlabeled uses of approved drugs. The AHFS DI is republished annually with three to four supplements per year.

The ANA DE is sponsored by the AMA, which represents over 293,000 physicians. The listed drugs include all drugs approved by the FDA for use in the United States. AMA staff prepare monographs after a literature search and review of FDA approved labeling. These monographs are reviewed by about 400 consultants followed by approximately 100 designees or members of the American Society for Clinical Pharmacology and Therapeutics. The review process continues until a consensus is developed. The AMA DE includes mostly general statements with truncated drug monographs including unlabeled uses of approved drugs. The AMA DE has been published every 3 years with updates. However, beginning in late 1989, the AMA plans to publish this copendium annually with quarterly updates.

Description of the List

[Table C-1] consists of IV drugs and their indications divided into three main categories. The categories are: biological, antibiotics and non antibiotics (which is further broken down as indicated above into the four subcategories of drugs, excluding for reasons discussed above antineoplastic drugs). The list is based on our analysis and evaluation of the recommendations and information received from the various professional organizations that we contacted. [Table C-2 contains a list] of the antibiotic drugs and indications not proposed for coverage.

We recognize that there is wide variation in both the type of drugs included in [table C-1] as well as the indications for these drugs. This is due in part to the fact that the concept of home IV therapy has evolved to treat diverse types of patients:

- Patients who began a course of IV therapy in the hospital that has not been completed, but who are stable enough to no longer require hospitalization.
- Patients who are terminally ill and require IV therapy, but whose condition does not warrant hospitalization.
- Other types of patients who require IV therapy but do not require hospitalization.

We are proposing that all candidates for home IV therapy meet specific selection criteria as outlined in the regulations referred to earlier that deal with coverage of home IV drug therapy services and conditions of participation for home IV drug therapy providers.

While many of the drugs on the proposed list can be safely and effectively administered in the home setting and would be covered, such medications are sometimes taken orally. Payment may be denied if a more appropriate route of administration is available. When deciding that the route of administration is appropriate, the Peer Review Organization (PRO) will carefully review to determine if another route of administration would be effective (for example, oral, subcutaneous, etc.). If the PRO makes a determination that another route would be effective, the PRO would deny payment. (An example might be: a physician seeking prior approval for the administration of intravenous Aminophylline.) Payment is made for home IV therapy only when it is reasonable and necessary and there is medical justification for its use.

The proposed list includes some very toxic drugs while other less toxic drugs are excluded. We note, however, that in urging us to include virtually all IV drugs on the list, some organizations we contacted took the position that "a drug is a drug, and a cell is a cell." These organizations believe a drug that can be administered in a hospital setting can also be administered in the home setting. We take a different view. There are a variety of factors that we have considered that play a role in the determination of whether a drug is safe and effective for use in the home. These factors include, in addition to the obvious factor of potential serious or life-threatening side effects, drug product stability and compatibility characteristics, and the need for close patient monitoring.

The variation of indications for each specific drug is a reflection of the varying degrees and stages of illnesses that will be treated in the home setting. We believe that we must allow flexibility to enable the physician to develop

a plan of treatment appropriate for the specific medical condition of the patient. Nevertheless, we wish to make clear that the appearance of an indication for a covered drug on the listing is not intended to imply that the indication is approved under the provisions of the FFDCA.

With respect to the specific working of the indications, because there are different phrases to describe the same disease states and conditions, there may appear to be inconsistencies in our use of medical terminology when listing indications. According to medical professionals and medical texts, the following terms are examples of terms that may be used interchangeably:

. Genitourinary infections with gynecological infections; and
. Skin and soft-tissue infections with skin and skin structure infections.

Also, there may be times when a specific indication could be considered as a subset of a larger classification. Examples of these would include:

• Cystitis as part of urinary tract **infections; and**
. Gonorrhea as part of genitourinary infections.

Such indications may have been listed separately in Appendix I because that is the way they appeared in the recommendations that we received. In addition, because the practice of medicine is dynamic, it would not be feasible to list all indications, either labeled or unlabeled, that are not suitable for treatment in the home. For this reason, we have listed the indications for each drug that can generally be treated safely and effectively in the home. The following indications are proposed for exclusion for all intravenous antibiotics because it is our understanding that the seriousness of the condition requires hospitalization.

1. Biliary tract infections.
2. Central nervous system infections.
3. Intra-abdominal infections.
4. Respiratory tract infections.
5. Septicemia.

Furthermore, specific labeled indications for certain drugs have been excluded because it is our understanding that they could not be safely and effectively treated intravenously in the home.

One of our proposed subcategories is "hydration therapy.' For our purposes and purposes of home IV therapy, the term is defined as the replacement of fluids or electrolytes, or both, in the human body when the physiologic and homeostatic mechanisms, which normally preserve their balance, fail as a result of illness or disease.

Most of the drugs that appear on the proposed list have specific dosages or dose ranges and are given at specific time intervals. For example, Cimetidine, used for hypersecretory conditions has a recommended dosing schedule of 300 mg administered intravenously every 6-8 hours. In comparison, for hydration therapy purposes, a physician can prescribe any of numerous available solutions used for this purpose, with the addition of one or more of the listed electrolytes, in a dose he or she has determined to be appropriate (for example, dextrose 5 percent in sodium chloride 0.45 percent, 1000 ml with 7 mEq of calcium as the chloride, gluconate or glucepate salt).

The magnitude of different combinations of ingredients in this subcategory requires our format for listing drugs in hydration therapy to differ from the other categories. This means that the options available to a physician prescribing a course of hydration therapy for a Medicare beneficiary would not be limited. The only restrictions on amounts of ingredients are those placed on solutions. These limitations have been determined to be the upper limits of commercially available products that would normally be used for hydration therapy (versus parenteral nutrition).

We are aware that our list will need periodic revision as new drugs are approved by FDA for entry in the marketplace. The FDA has informed us that 10-20 new IV drugs are approved over the course of each year that we would have to consider for entry on the list. In addition, if a drug already on the list is removed from the market or if a drug is no longer considered to be appropriate for home use, we would delete the drug from the list. We will update the list at least annually through a notice in the ***Federal Register.*** Updates may occur more frequently, possible as often as semi-annually.

Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed notice that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Also, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (REA) (5U.S.C. 601 through 612) unless the Secretary certifies that a proposed notice would not have a

significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmaceutical manufacturers and physicians are considered small entities.

As noted earlier in this preamble, this notice addresses the issues of:

1. Identifying IV drugs (both antibiotics and non-antibiotics) and their indications that are approved for marketing by FDA; and
2. Identifying those IV drugs that are safe and effective for use in the home. There maybe some economic or other effects of the proposed list of drugs that may touch upon other proposed rules implementing other home IV provisions of the catastrophic legislation, and some of these effects are addressed here as well as in the other rules. The purpose of this duplication is to ensure that the reader may determine the effects of each document without referring to the other proposed documents.

In addressing the first issue discussed above, all of the IV drugs listed in this notice may be covered under Medicare as covered outpatient drugs because they meet the criteria defined in section 1861(t)(2) of the Act. Thus, HCFA has exercised no administrative discretion in this area.

Administrative discretion, however, was required to identify those IV drugs that are safe and effective for use in the home. As discussed earlier in this preamble, we contacted the USP, ASHP, AMA, various home IV providers, the Pharmaceutical Manufacturers Association, various drug manufacturers and the Intravenous Nurses Society in making our initial determination as to whether a certain IV drug could be proposed as safe and effective for use in the home. We believe that the information solicited from the compendia along with the advice of the other organizations constitutes a valid basis on which to conclude with reasonable assurance that a particular drug can generally be administered safely and effectively in a home setting. Furthermore, we believe that the identification of IV drugs that are safe and effective for use in the home would not result in any significant effects on the economy or on small businesses. Our reasons follow:

Effects on Drug Manufacturers-Drug manufacturers producing IV drugs that are included in this proposed list would be advantaged in competing for the Medicare market because their drugs would be covered under Medicare as home IV drugs. We recognize that manufacturers producing IV drugs that are not included in our proposed list would be adversely affected in competing for the Medicare share of the IV drug market. Although we do not have data available that allow us to determine the degree to which drug manufacturers would be affected, we do not believe **that will be significantly affected. This is because IV drugs (except antineoplastics) currently being prescribed for home use would likely be included on the proposed list based on the methodology used in developing this list.**

Effects on Beneficiaries-Medicare beneficiaries who are prescribed an IV drug for home use that is on the proposed list would benefit by being eligible for Medicare coverage of that drug. Conversely, beneficiaries for whom a drug has been prescribed that is not covered by Medicare for home IV use may have to remain in the hospital to receive covered IV therapy or may have to incur expenses for home IV therapy themselves. Since we believe that most drugs currently prescribed for home IV use are included on the list, we do not believe beneficiaries would be significantly affected adversely.

Effects on Physician-If drugs commonly prescribed by a physician for use in the home are not on the list, the physician could be influenced to change his or her prescribing patterns for Medicare patients to ensure that the patient is prescribed a Medicare covered home IV drug. However, given that we have consulted with various professional organizations and compendia in developing this list, we believe that the list, with the exception of antineoplastices, contains the most frequently prescribed home IV therapy drugs. Thus, we believe it unlikely that physicians' prescribing patterns would change significantly as a result of this list.

For the reasons discussed above, we believe that this notice would not meet the $100 million criterion nor do we believe that it meets the other E.O. 12291 criteria. Therefore, we have determined that this notice is not a major rulemaking document under E.O. 12291, and a regulatory impact analysis is not required. Also, for the reasons discussed, we have determined, and the Secretary certifies, that this notice would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis would not be required under RFA.

Payment for Covered Outpatient Drugs (54 F.R. 37208)

This proposed rule sets forth the methodology for determin ing payment for covered outpatient drugs under the new catastrophic drug benefit. This proposal would implement sections 1834 (c)(2), (3), and (4) of the Social Security Act as added by section 202(b) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for these covered outpatient drugs under Part B of Medicare would be implemented on January 1, 1990 for drugs used in immunosuppressive therapy and covered home intravenous (IV) drugs and on January 1, 1991 for all other drugs.

Purpose

This subpart implements section 1834(c) of the Act in part by specifying how payments are made for covered outpatient drugs under the catastrophic drug benefit.

Definitions

For purposes of this subpart, the following definitions apply: ***Average price*** means the price that is determined through the use of either published or survey data concerning amounts pharmacies pay for drug products. ***Multiple source drug*** means a covered outpatient drug for which there are two or more drug products that meet all of the following conditions during payment calculation period:

(a) Therapeutically equivalent. The drug products are rated as therapeutically equivalent by the Food and Drug Administration (FDA) in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations. "

(b) Pharmaceutically equivalent and bioequivalent
(1) Except as provided in paragraph (b)(2) of this section, the drug products have been determined by FDA to be pharmaceutically equivalent and bioequivalent.
(2) The drug products are not required to meet the condition concerning pharmaceutically equivalency and bioequivalency as set forth in paragraph (b)(l) of this section if FDA changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for Purposes of the Approved Drug Products with Therapeutic Equivalence Evaluations," in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.

(c) Available for sale or marketing. The drug products are considered to be available for sale or marketing. Drug products meet this condition if they are listed by FDA in its most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations" (other than in the Discontinued Drug Product List in the publication) unless HCFA determines that sale or marketing is not actually occurring.

Nonmultiple-source drug means a covered outpatient drug that does not meet the definition of a "multiple-source drug." Payment calculation period means the 6-month period beginning January 1st of each year or the 6-month period beginning July 1st of each year.

Determination of Amount Payable

(a) General. The amount payable for a covered outpatient drug under the catastrophic drug benefit as described in 410.29 of this chapter is the applicable payment percent for the drug as determined under 414.514 multiplied by the lesser of:
(1) The actual charge; or
(2) The payment limit determined under 414.506.

(b) Effective date. Payment is determined under the criteria described in paragraph (a) of this section for:
(1) Drugs dispensed for immunosuppressive therapy after a transplant or covered home IV drugs on or after January 1, 1990; and
(2) All other covered outpatient drugs dispensed on or after January 1, 1991.

Determination of the Payment Limit

(a) General. To determine the payment limit for a drug, HCFA uses the procedures set forth in paragraph (b) or (c) or this section.

(b) Nonmultiple-source drug and multiple-source drug with a restrictive prescription. For a nonmultiple-source drug and multiple-source drug with a restrictive prescription as described in 414.508, the payment limit is determined as follows:

(1) For drugs dispensed on or after January 1, 1990 and before January 1, 1992, the payment limit is equal to the sum of:
(i) The amount of the administrative allowance as set forth in 414.512; and
(ii) The product of the number of tablets or other dosage units dispensed and the dosage unit average price as determined in 414.510 for the payment calculation period in which the drug is dispensed.

(2) For drugs dispensed on or after January 1, 1992, the payment limit is equal to the lesser of:
(i) The amount of the administrative allowance plus the product of number of tablets or other dosage units dispensed and the average price per dosage unit determined under 414.510 for the payment calculation period in which the drug is dispensed; or
(ii) The 90th percentile of actual charges for a drug for the second previous payment calculation period or other dosage units dispensed.

(c) Multiple-source drug without a restrictive prescription. For a multiple-source drug without a restrictive prescription, the payment limit is equal to the sum of:

(1) The administrative allowance; and
(2) The product of the number of tablets or other dosage units dispensed and the dosage unit average price based on the unweighed median determined under 414.510 for the payment calculation period in which the drug is dispensed.

Determining Whether a Prescription Is Restrictive:

(a) General. A drug has a restrictive prescription if it meets the conditions set forth in either paragraph (b) or paragraph (c)of this section.

(b) Handwritten prescription. In the case of a written prescription for a drug, only if the prescribing physician (or other person prescribing the drug) includes in his or her handwriting the phrase "brand medically necessary.'

(c) Telephoned prescription. In the case of a prescription for a drug that is telephoned to-the pharmacy, the prescribing physician (or other legally authorized person who is prescribing the drug) indicates that the particular drug must be dispensed by stating the phrase "brand medically necessary" both:
(1) During the telephone call; and
(2) Within 30 days after the telephone call, in a written and signed confirmation, in his or her handwriting to the pharmacy.

Determination of Dosage Unit Average Price

(a) General. HCFA determines the average price on a per dosage unit basis for purchases in reasonable quantities, as appropriate, based on prices in effect on the first day of the previous payment calculation period. The average price is based on dosage form and strength for each drug product.

(b) Sources for dosage unit average price. HCFA obtains the information described in paragraph (a) of this section from the lower of:
(1) When available, a biannual survey of a representative sample of direct sellers, wholesalers, or pharmacies as appropriate; or
(2) Prices published in commonly recognized, comprehensive listings of drug prices.

(c) Performance of surveys.
(1) Nonmultiple-source drugs.
(i) HCFA performs the biannual survey described in paragraph (b)(1) of this section for those nonmultiple-source drugs that are commonly prescribed to Medicare beneficiaries except that this survey does not have to be performed in:
(A) Any year in which HCFA determines that a survey is not appropriate for a specific covered outpatient drug; or
(B) In years subsequent to 1990, any year in which HCFA determines that there is a low volume of sales for a drug.
(ii) The dosage unit average price is based on the median of the surveyed prices.
(2) Multiple-source drugs. HCFA performs the biannual survey described in paragraph (b)(1) of this section for multiple-source drugs, but only if HCFA determines a survey to be appropriate. The dosage unit average price is based on the unweighed median of the surveyed prices.

(d) Use of published prices.
(1) Nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions. The dosage unit average price for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions is based on the lowest published price.
(2) Multiple-source drugs without restrictive prescriptions. The dosage unit average price for multiple-source drugs without restrictive prescriptions is based on the unweighed median of published prices.

(e) National determination. The determination of the dosage unit average price is made on a national basis unless HCFA makes the determination on a regional basis to take into account limitations on the availability of drugs and variations on the prices among different areas.

(f) Discounts. In determiningg the dosage unit average price, HCFA does not consider discounts.

Administrative Allowance

(a) For 1990 and 1991. For a drug dispensed on or after January 1, 1990 and before January 1, 1992, the administrative allowance for dispensing the drug is:
(1) $4.50 per prescription for a pharmacy that meets the requirements under subpart B of part 490 of this chapter for a participating pharmacy; or
(2) $2.50 per prescription for a pharmacy that is not a participating pharmacy.

(b) For years subsequent to 1991. For each year subsequent to 1991, the administrative allowance is the allowance applicable to the previous year increased by the percentage increase in the implicit price deflator for gross national product over the 12 month period ending with August of the preceding year as published by the Department of Commerce rounded to the nearest penny.

(c) Limitation on administrative allowance for dispensing insulin.
(1) Purchase of a 30 day supply. For insulin that is available without a prescription, the administrative allowance is made for each purchase of a reasonable quantity, that is, a 30 day supply.
(2) Exceptions. An administrative allowance is made for a purchase of a supply of insulin for fewer than 30 days in the following circumstances (or if other extenuating conditions exist):
(i) There is a change in the type of insulin the beneficiary uses or the insulin regimen is otherwise modifies; or
(ii) If, because of travel plans, the beneficiary needs to make smaller purchases or forgets to bring along enough insulin for duration of the trip.

(d) Exception for drugs dispensed for home IV drug therapy. No administrative allowance is paid for dispensing a drug that is to be used in home IV drug therapy. An allowance for dispensing IV drugs is made under the fee schedule for payment for services related to home IV drug therapy under subpart J of part 414.

Amount of the Payment Percent

(a) Immunosuppressive and home IV drugs. **For drugs related to immunosuppressive drug therapy dispensed during the first year after a covered organ transplant and for home IV drugs, the payment percent equals 80 percent.**

(b) Other drugs. The payment percent for covered outpatient drugs other than the drugs described in paragraph (a) of this section equals the following:
(1) In 1990 and 1991,50 percent.
(2) In 1992,60 percent.
(3) In 1993 and subsequent years, 80 percent.

Coverage of Home Intravenous Drug Therapy Services (54 F.R. 37422)

These **proposed regulations would expand coverage under Medicare Part B to include coverage of home IV drug therapy services as authorized by section 203 of the Medicare Catastrophic Coverage Act of 1988. They include requirements for certification and for review and approval of the need for the covered services by a peer review organization, and they place limits on acceptance of and payments for certain patient referrals for covered home IV drug therapy services as specified in the statute. Home IV drug therapy services are covered by Medicare beginning January 1, 1990.**

Basic Rule

Under sections 1834(d) and 1861(jj), Medicare Part B pays for home intravenous drug therapy services furnished by a qualified home intravenous drug therapy provider (see part 485, subpart C of this chapter) or by others under arrangements made by the qualified home IV drug therapy provider with them, to a patient who is under the care of a physician, in a place of residence used as the beneficiary's home and under a plan of care established and periodically reviewed by the beneficiary's referring physician.

Definitions

For purposes of this subpart:

Home intravenous drug therapy provider or "home IV provider" means an entity that provides home IV drug therapy services, has been certified as meeting the conditions of participation of part 485, subpart C of this chapter, and has a provider agreement with HCFA.

Home intravenous drug therapy services or "home IV services" means nursing, pharmacy and related services (including medical supplies, equipment, intravenous fluids only when used as diluents for covered home IV drugs, and delivery services) necessary to conduct an intravenously administered regimen safely and effectively in conjunction with the use of a covered home intravenous drug. These services are furnished to an individual who is under the care of a physician, in a place of residence used as the individual's home, by a qualified home IV provider (or by others under arrangements), and under a plan established and periodically reviewed by the referring physician.

IV stands for intravenous.

Place of residence used as the individual's home is a place in which the beneficiary normally resides and is not an institution or facility that is defined in section 1861(e)(l), 1819(a) or 1919(a) of the Act.

Referring physician means the physician who prescribed the covered home intravenous drug for which the services are to be provided or who established the plan of care for the services or both.

Home IV Drug Therapy Services

(a) Individual services. Particular services included in the term "home intravenous drug therapy services' that are covered under this subpart are limited to the nursing services and pharmacy services described in 485.135 and 485.140, respectively, of this chapter and related services described in paragraph (b) of this section that are necessary for the safe and effective administration of a covered home IV drug. Separate payment may not be made for any of these services furnished to

a patient receiving covered home intravenous drug therapy services.

(b) Related services and supplies. The home IV provider must furnish the following if they are necessary for the safe and effective administration of a covered home IV drug:
(1) Medical supplies;
(2) Intravenous fluids for use as diluents for covered home IV chug;
(3) Training of the patient or his or her caregiver in the techniques of IV drug therapy;
(4) Equipment such as IV poles and infusion pumps; and
(5) Delivery of medical items and supplies.

(c) Prohibited payment. Payment may not by made to a home IV provider for covered home IV drug therapy services unless the home IV provider furnishes the covered home IV drug either directly or under arrangements.

Payment Limitations Concerning Certain Patient Referrals

(a) Ownership and compensation rules. Payment may not be made to a home IV therapy provider for the home IV drug therapy services furnished to a beneficiary if that beneficiary's referring physician or an immediate member of the referring physician's family has an ownership interest in the provider or receives compensation from the provider unless an exception under paragraph (b) through (e) of this section applies. For purposes of this paragraph, an immediate member of the family includes the physician's spouse; natural and adoptive parents, natural and adopted children; natural, adopted, and adoptive siblings; stepparents, stepchildren, and step siblings; fathers-in-law, mothers-in-law, brothers-in-law, sisters-in-law, sons-in-law, and daughters-in-law; and grandparents and grandchildren.

(b) Exception applying to limitation on ownership.
(1) Payments may be made if the ownership interest is the ownership of stock in the home IV provider that is traded over a publicly regulated exchange and purchased on terms generally available to the public.
(2) Payments may be made if the provider is the sole home IV drug therapy provider in a rural area.
(3) For purposes of paragraph (b)(2) of this section, a rural area is one that is not an urbanized area (as defined by the Bureau of the Census) and that is designated by the Secretary either:
(i) As an area with a shortage of personal health services under section 1302(7) of the Public Health Service Act, or
(ii) As a health manpower shortage area described in section 332(a)(l)(A) of the Act because of its shortage of primary medical care manpower.
(4) For purposes of paragraph (b)(2) of this section, a sole home IV drug therapy provider in a rural area is one that is approved as such by HCFA after the provider:
(i) Designates a particular area;
(ii) Shows that no other home IV provider furnishes services within that area [and]
(iii) Shows that there are no physicians without an ownership interest in the provider available to perform certification and recertification and to write plans of care.

(c) Exception applying to limitation on compensation. Payment may be made under this section if the compensation is reasonably related to items or services actually provided by the physician and does not vary in proportion to the number of referrals made by the referring physician. This exception does not apply if the compensation is for direct patient care services.

(d) Exception applying to uncompensated officer or director. Payment maybe made if the referring physician's or immediate family member's ownership or financial relationship with the provider is as an uncompensated officer or director of the provider.

(e) Exceptions applying to instances in which there is not substantial risk of program abuse. Payment may be made under this part in those cases in which the Secretary has specifically determined that the nature of the ownership or compensation does not pose a substantial risk of program abuse involving the following:
(1) Space rental. For purposes of this paragraph, the term ''fair market value" means the value of the rental property for general commercial Purpose (not taking account of its intended use), but it is not adjusted to reflect the additional value the prospective lessee or lessor value would attribute to the property as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. As used in section 1834(d) of the Act, neither "ownership" nor "compensation" includes payments made by a lessee to a lessor for the use of premises, as long as:
(i) The lease agreement is set out in writing and signed by the parties;
(ii) The lease specifies the premises covered

by the lease;

(iii) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, their periodicity, and the exact rent for such intervals;

(iv) The term of the lease is for not less than 1 year; and

(v) The rental charge is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals of business between the parties for whom the services would be paid by Medicare or Medicaid.

(2) Equipment rental. For purposes of this paragraph, the term "fair market value" means the value of the equipment when obtained from a manufacturer or professional distributor, but it is not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the equipment as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. As used in section 1834(d) of the Act, neither "ownership" nor "compensation" includes payments made by a lessee of equipment to the owner (' 'lessor' of the equipment for the use of the equipment, as long as:

(i) The lease agreement is set out in writing and signed by the parties;

(ii) The lease specifies the equipment covered by the lease;

(iii) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, their periodicity, and the exact rent for such intervals;

(iv) The term of the lease is for not less than 1 year; and

(v) The rental charge is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals of business between the parties reimbursed under Medicare.

(3) Personal services and management contracts. For purposes of this paragraph, an agent of a principal is any person, other than a bona fide employee, who has an agreement to perform services for, or on behalf of, the principal. As used in section 1834(d) of the Act, neither "ownership" nor "compensation" includes payments made by a principal to an agent as compensation for the services of the agent, as long as:

(i) The agency agreement is set out in writing and signed by the parties:

(ii) The agency agreement specifies the services to be provided by the agent;

(iii) If the agency agreement is intended to provide for the services of the agent on periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, the periodicity, and the exact charge for such intervals;

(iv) The term of the agreement is for not less than 1 year; and

(v) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in manner that takes into account the volume or value of any referrals of business between the parties that is reimbursed under Medicare or any State health care program.

(4) Employees. As used in section 1834(d) of the Act, neither "ownership" nor "compensation" includes any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the provision of covered items or services. For purposes of this paragraph (f)(4), the term "employee" has the same meaning as it does for purposes of 42 U.S.C. 410(j)(2), part of the statutory definition of "employee'' in the Federal Insurance Contributions Act; that is, the common law employment test.

Physician Certification and Plan of Treatment Requirements

Medicare Part B pays for home intravenous drug therapy services only if the referring physician certifies, and recertifies as required under paragraph (b) of this section, that the requirements described in paragraphs (a)(1) through (a)(5) of this section are being met.

(a) Certification: Content. The referring physician must certify, or recertify if applicable, that:

(1) The home intravenous drug therapy services

are or were required because the individual needs or needed the services for the administration of a covered home intravenous drug;

(2) A plan for furnishing the services has been established by the referring physician and is reviewed periodically by that physician;

(3) The services are or were furnished while the individual is or was under the care of a physician;

(4) The services are furnished in a place of residence used as the patient's home; and

(5) For services initiated before January 1, 1993, a PRO has approved the services in accordance with part 466, subpart E, of this chapter.

(b) Recertification. The referring physician must recertify that the requirements in paragraph (a) of this section are still met at least every 30 days.

(c) Plan of care requirements.

(1) Establishment. The referring physician must establish and sign the plan of care and consult as necessary with the home IV provider nurse or pharmacist before the home IV Therapy begins in accordance with sections 485.135 and 485.140 of this chapter.

(2) Content. The plan of care must contain at least the information required in section 485.120 of this chapter.

(3) Review. The physician must review and sign the plan of care at least every 30 days.

PRO Review of Home IV Drug Therapy Services

(a) Statutory basis. Sections l154(a)(16) and 1835(a)(2)(G) of the Act require PROS to review all home intravenous (IV) drug therapy services before these services begin; or, in the case of services first initiated on an outpatient basis, within one working day (other than in exceptional circumstances) of the date of initiation of the services.

(b) Applicability. The regulations in this subpart apply to reviews, conducted by a PRO and its subcontractors, of home IV drug therapy services furnished, or proposed to be furnished to all Medicare beneficiaries other than those beneficiaries enrolled in HMOs [health maintenance organizations] or CMPs [competitive medical plans] that contract with HCFA on a risk-basis as described in subpart C of 42 CFR part 417.

Effective Dates-All home IV drug therapy services intended to be furnished to Medicare beneficiaries on or after January 1, 1990 are subject to the PRO review requirements of this subpart.

Definitions-As used in this subpart:

Outpatient basis means the patient receives services other than as an inpatient of a hospital.

Scope of PRO Review—

(a) General rule. After a PRO receives a request for review of home IV drug therapy services from either the referring physician or the health care facility, the PRO must determine (in accordance with the terms of its contract) whether the home IV drug therapy is reasonable, appropriate, and necessary for the treatment of the illness or injury. This review includes a determination that the intravenous route of administration is the correct route of administration and that the home IV drug therapy services meet professionally recognized standards of care.

(b) Coordination of sanction activities. In implementing review of home IV drug therapy services, PROS must carry out the responsibilities specified in subpart C, part 1004, chapter V of this title, regarding imposition of sanctions on health care facilities and practitioners who violate their statutory obligations under Section 1156 of the Act. For example, a PRO is to refer to the HHS [U.S. Department of Health and Human Services] Office **of** Inspector General a case involving a physician who exhibits a pattern of not correctly monitoring, by appropriate laboratory tests, the administration of a drug.

Notification of PRO Review Procedures-

(a) Criteria. The PRO must distribute, at no charge, the criteria/quality screening guidelines to be used in screening cases, at a minimum, to all affected health care facilities and medical societies in the State.

(b) Information required. Each PRO must give timely written notification to health care facilities and physicians in its State the following information:

(1) Date. The date upon which the PRO plans to begin review of home IV drug therapy services.

(2) Manner. The manner in which the referring physician or health care facility is to seek PRO review.

(3) Required information. The **information to be furnished to the PRO by the physician and/or health care facility and the need for expediency in responding to PRO questions.**

(4) Validation and quality review. The validation and quality review that the PRO may conduct on a sample of the cases after the services are furnished in the home.

(5) Financial liability. A general statement about

financial liability for charges related to home IV drug therapy services that are found to be not reasonable or medically necessary and a statement that no claims will be paid without PRO approval.

Responsibilities of Physicians and Health Care Facilities—

(a) Physicians. The referring physician must cooperate (in addition to the requirements in 466.78) in the conduct of PRO review as follows:
(1) The physician must, in accordance with PRO-issued procedures, either seek PRO prior authorization for the drug he or she proposes to have administered intravenously at home or assist in providing necessary information in support of a health care facility that seeks PRO approval.
(2) The physician must furnish relevant medical records, upon request, to the PRO for any of the reviews described in this subpart.

(b) Health care facilities.
(1) In addition to the general requirements for health care facilities set forth in 466.78, the health care facility must cooperate in the conduct of PRO review (in accordance with the regulations in this part and PRO-issued procedures) by obtaining the authorization number provided by the PRO:
(i) Before beginning the administration of an IV drug in the patient's home, except in cases where the drug is to be started on an outpatient basis on a weekend (i.e., a non-workday), the authorization must be obtained the first working day thereafter; and
(ii) In certain cases, before continuation of home IV drug therapy that the PRO has previously approved as described in 466.216 (c) and (d).
(2) Health care facilities must maintain a written agreement with the appropriate PRO.
(3) The health care facility must, in accordance with PRO-issued procedures, either seek PRO approval of the IV drug therapy services proposed to be administered at home or assist in providing necessary information in support of a referring physician that seeks PRO approval.
(4) The health care facility must transfer relevant medical records (including the plan of care described in 424.28(c)), upon request, to the PRO for any of the reviews described in this subpart.

Lack of Cooperation by a Health Care Facility or Physician—If a health care facility or physician fails to comply with the requirements for review set forth in this subpart, the PRO may determine that the health care facility or physician has failed to comply with the requirements of subpart C, part 1004, chapter V of this title concerning failure by providers or practitioners to meet statutory obligations under section 1156 of the Act and may report the matter to the Office of Inspector General.

PRO Designation—
(a) When-home IV drug therapy is proposed for a currently hospitalized inpatient, the referring physician or health care facility must contact, for prior authorization, the PRO with whom the hospital has an agreement.

(b) When home IV drug therapy is proposed for a patient who has had the drug started on an outpatient basis, the physician or health care facility must contact, for authorization, the PRO for the State in which the home IV drug therapy provider is located.

(c) For all other reviews, the PRO for the State in which the home IV drug therapy provider is located will conduct the review.

PRO Approval—
(a) Before approving the home IV drug therapy services, the PRO must assured:
(1) **That the** patient's condition is such that inpatient hospitalization is not justified either

(i) As a continuation of an existing hospitalization; or
(ii) As a medically necessary and appropriate admission;
(2) Orally, in writing, or from documentation (or any combination of these three), that the patient meets the selection criteria outlined in 485.115 of this subpart;
(3) That the patient or caregiver has been or will be sufficiently trained as to how to administer the drugs safely and effectively in the home; and
(4) That the patient or caregiver has or will independently administer(e-d) intravenously at least one dose of the drug under supervision.

(b) The PRO must determine that:
(1) The plan of care, executed by the referring physician, has enough information to support the coverage of home IV drug therapy services;
(2) The drug is being used for one of the stated indications listed in a ***Federal Register*** notice issued by the Secretary;

(3) The drug is medically indicated for the treatment of the patient's condition;
(4) The dosage is correct (e.g., adjusted for height and body weight);
(5) Appropriate diagnostic studies (e.g., culture and sensitivities, kidney function tests) have been performed and will be performed as appropriate while the patient is receiving the therapy;
(6) Other appropriate periodic monitoring has been and will be performed;
(7) The drug is not contraindicated (e.g., based upon abnormal laboratory findings, or drug interactions); and
(8) The home IV drug therapy services meet professionally recognized standards of care.

(c) The PRO must also determine that the intravenous route of administration is the only route of administration that will be effective.

(d) In performing review, the PRO uses review coordinators to compare the facts about the individual case to the criteria/screening guidelines developed by HCFA, the PRO, or both.
(1) If the case meets the criteria/guidelines, the review coordinator issues a PRO approval number.
(2) If the case does not meet the criteria/guidelines, the review coordinator refers the case to a PRO physician.
(3) The PRO physician review either approves the case (using a PRO approval number) or questions the case.
(4) If the case is questioned by the PRO physician, the physician who prescribed the home IV drug therapy and the health care facility are immediately given an opportunity to discuss the case.
(i) The PRO attempts to contact either the referring physician or health care facility.
(ii) The referring physician may discuss the case with a PRO physician.
(iii) The health care facility may discuss the case with a PRO representative. If, however, the health care facility designates a physician representative, the physician may also discuss the case with a PRO physician.
(iv) For potential quality problems, the PRO **follows the timeframes outlined in its contract with HCFA.**

Timing of Review—

(a) Prior review of continuation of inpatient hospital therapy.
(1) The PRO is required, for all IV drug therapy continued at home after a hospital stay, to authorize such use before hospital discharge.
(2) The review must be requested by the referring physician or the health care facility in accordance with PRO-issued instructions.
(3) The PRO will follow the review process outlined in 466.214(c).
(4) The PRO must complete the review within one working day of receipt of a request for review.
(i) The date of the request for review is considered to be the date upon which the PRO receives all of the information it needs to complete the review.
(ii) In this timeframe, the PRO must give the health care facility and referring physician an opportunity to discuss the case as described in 466.214.
(iii) Failure of the health care facility and referring physician to discuss the case within the time allowed is not a basis that will prevent the PRO form making its determination base upon the information in its possession.

(b) Initial review of IV drugs started on an outpatient basis. In the case of a patient whose IV drug therapy services are initiated on an outpatient basis, the referring physician or health care facility will request PRO approval no later than the first working day on which the home IV drug therapy services are prescribed.
(1) The PRO has 8 working hours in which to complete its review after receipt of a request for review from the referring physician or health care facility.
(2) The date the PRO receives the request for review is the date on which the PRO receives all the information it needs to complete the review.
(3) PRO review follows a request from the referring physician or health care facility that is made in accordance with PRO-issued instructions.
(4) The PRO will follow the review process outlined in 466.214(c).
(5) The PRO must complete its review within 1 working day of initiation for the home IV drug services.
(i) This timeframe includes the time the PRO must give the health care facility and physician to discuss the case as described in 466.214.
(ii) If the health care facility and physician do not take advantage of the opportunity to discuss the review within the time allowed the PRO may make its determination

based upon the information in its possession.

(c) Subsequent reviews for continuation of drugs. In accordance with the PRO's prior approval, when drugs are to be continued for a period of time beyond the date or number of days approved by the PRO, the PRO will periodically review to determine that coverage of the home IV drug therapy services continues to be appropriate in accordance with the requirements set forth in 466.214(a) and (b) of this subpart.

(1) If home IV drug therapy is planned to continue for a time past the date the PRO has indicated, the physician or health care facility must request PRO review no less than 3 working days before the expiration of the current PRO approval.

(2) The PRO follows the process outline in 466.214(c).

(3) The PRO must complete subsequent reviews within ***3*** working days for the request.

(i) In this timeframe, the PRO must give the health care facility, if applicable, and physician an opportunity to discuss the case as described in 466.214.

(ii) If the health care facility and physician do not take advantage of the opportunity to discuss with the tie allowed, the PRO may make its determination based upon the information in its possession.

(d) Prior review of change in drug. When the referring physician proposes a change to the IV drug therapy, the referring physician or the health care facility will request PRO approval of the revision in therapy within one working day of initiation of the change.

(1) The referring physician or health care facility must request PRO review in accordance with PRO-issued instruction.

(2) The PRO will follow the review process outlined in 466.214(c).

(3) The PRO will complete its review within three working days of the request.

(i) In this timeframe, the PRO must afford the health care facility and referring physician an opportunity to discuss the case as described in 466.214.

(ii) If the health care facility and referring physician do not take advantage of the opportunity to discuss the case within the time allowed, the PRO will make its determination based upon the information in its possession.

(e) Retrospective reviews. For retrospective reviews, the PRO must adhere to the timing of review requirements found in its contract with HCFA.

Notification—

(a) The PRO must, within the timeframes given in 466.216, provide notification if its determination as follows:

(1) The PRO notifies the health care facility and referring physician by telephone as to whether it has determined that:

(i) Services are reasonable, appropriate, and medically necessary. The PRO issues an approval number and informs the health care facility, if applicable, and referring physician of the date by which review and subsequent approval must be requested for continuation of the IV drug therapy;

(ii) Services are not reasonable, appropriate, or medically necessary;

(iii) Services are medically necessary but neither the patient nor caregiver meets the selection criteria; or

(iv) The patient should receive the services if another setting.

(2) If the PRO does not authorize the services because they are not reasonable, appropriate and medically necessary in the home setting, within 1 working day of the determination it must, in accordance with the requirements of section 466.94(c), notify in writing:

(i) The beneficiary;

(ii) The referring physician;

(iii) The health care facility, and

(iv) The fiscal intermediary.

(b) If the PRO determines that the services do not meet professionally recognized standards of care, the PRO will notify the referring physician and health care facility in accordance with the quality intervention plan in the PRO's contract.

Retrospective Reviews-

(a) Random sampling. The PRO must periodically review a sample of cases to determine that the home IV therapy services meet professionally recognized standards of care and that the conditions in 466.214 are met.

(b) Retrospective review of unapproved cases. On a retrospective, prepayment (and on an exception basis, postpayment) basis, the PRO reviews (upon the request of the physician or health care facility) any claims for the home IV drug therapy services for which PRO review was required but never completed and makes a determination in accordance with 466.214.

(c) Validation reviews. The PRO in the State where the home IV drug therapy provider is located must

conduct a validation review of a sample of cases in which approval for home IV drug therapy services under this subpart was granted by telephone tier the PRO considered medical information by telephone but did not review actual medical records.

(1) The PRO must be assured that information provided to the PRO was accurate and that the home IV drug therapy services met professionally recognized standards of care.

(2) If inaccurate information was given to the PRO, the PRO must deny payment for the services if they are found to be uncovered based upon the correct information.

(3) As a result of this review, the PRO may decide that future medical information must be submitted in writing.

Liability and Sanctions for Unreviewed Cases—

(a) Payment contingent upon approval. No payment will be paid for any claim where the PRO has not approved the services for payment.

(b) Failure of PRO to complete review. If, because of a PRO administrative error, the review is not completed within the timeframes outlined in 466.216, the PRO still must complete the review and issue an approval number or a notice denying the services.

(c) Financial liability. Financial liability is determined in accordance with provisions of sections 1842(1) and 1879 of the Act and 405.330 through 405.336 of this chapter.

(d) Corrective action.

(1) If the review is not completed timely, whether or not the PRO determines that the home IV drug therapy is appropriate and the physician or health care facility (or both) are the cause of the problem (including failure to make the request on a timely basis), the PRO must take whatever corrective actions are necessary to ensure that future cases are reported to the PRO for review within the outlined timeframes.

(2) If the information given over the telephone is found to be inaccurate or misleading, the PRO may take appropriate corrective actions.

Reconsiderations and Appeals Reconsiderations and appeals are available under part 473 **of this** chapter for all PRO initial denial determinations.

Location for Submitting Requests for Reconsideration—

(c) Expedited reconsideration. A request for an expedited reconsideration must be submitted directly to the PRO if the denial is a result of:

(1) Preadmission/preprocedure review; or

(2) Review of home intravenous drug therapy services before the initiation of or during the period in which the beneficiary is still receiving the services.

Time Limits for Issuance of the Reconsidered Determination—

(a) Beneficiaries. If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits:

(1) Within 3 working days after the PRO receives the request for reconsideration if:

(i) The beneficiary is still An inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to home intravenous drug therapy services for which approval was denied and a request was submitted timely for an expedited reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if:

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF [skilled nursing facility] for the stay in question or no longer receives home intravenous drug therapy services for which the PRO issued a denial determination; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely [sic].

Payment for Home Intravenous Drug Therapy Services (54 F.R. 46938)

This proposed rule sets forth the methodology for payment for home IV drug therapy services. This proposal would implement the provisions of section 1834(d) of the Social Security Act as added by section 203(c)(1) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for home IV drug therapy services under Part B of Medicare would be implemented on January 1, 1990.

Basis and Scope

(a) Statutory basis. This subpart is based on sections 1834(d)(l) and (2) of the Act which, respectively:

(1) Provide that payment for home IV drug therapy services is the lesser of the actual charges or a fee schedule amount; and

(2) Require the Secretary to establish by regulation a per diem fee schedule for those services.

(b) **Scope. This** subpart sets forth the methodology used to determine the per diem fee schedule amount for home IV drug therapy services, which are covered under Medicare beginning on January 1, 1990.

Determination **of Amount Payable**

(a) **General** rule. Medicare payment for home IV drug therapy services, as defined in section 410.203 of this chapter, is made at 100 percent of the lesser of:
(1) The actual charge; or
(2) The applicable per diem fee schedule amount and any applicable additional allowances determined under this subpart.

(b) Separate fee schedules. Two separate fee schedule amounts are calculated; one for pain management drug therapy and one for antibiotic and other drug therapies.

(c) Basis for calculating fee schedule amounts. The applicable fee schedule amount for each type of drug therapy is the per diem allowance for each of the home IV drug therapy service components plus, as appropriate, additional allowances applicable in special circumstances.

(d) Service components. HCFA calculates a per diem fee schedule allowance for each of the following:
(1) Pharmacy services.
(2) Pharmacy supplies.
(3) Pharmacy delivery.
(4) Nursing services and supplies.
(5) Other equipment.

(e) Special circumstances. HCFA calculates additional allowances for each of the following:
(1) Patient education and counseling at the time IV drug therapy begins in the home
(2) Multiple IV drug regimen.
(3) New drug introduced into existing drug regimen.

Calculation **of Per Diem Fee Schedule Allowances for Calendar Year 1990**

(a) Pharmacy services.
(1) An average hourly pharmacy rate is calculated by weighting an average hourly pharmacist rate based on direct and indirect costs and an average hourly pharmacy technician rate based on direct and indirect costs by the estimated time spent by each in drug preparation.
(2) A per dose cost of preparation is calculated for each type of drug by multiplying the average time spent in preparing the drug and evaluating patient outcome by the average hourly pharmacy rate.
(3) A per diem cost of preparation is calculated for each type of drug by multiplying the per dose cost for the drug by the average number of doses per day.
(4) The per diem allowance for pharmacy services for each type of drug therapy is equal to the per diem cost of preparing that type of drug.

(b) Pharmacy supplies.
(1) A per dose cost of pharmacy supplies for each type of drug therapy is calculated by adding the cost of all supplies needed for that type of therapy.
(2) A per diem cost of pharmacy supplies for each type of drug therapy is calculated by multiplying the per dose cost by the average number of doses per day.
(3) The per diem allowance for pharmacy supplies for each type of drug therapy is equal to the per diem cost for supplies for that type of drug therapy.

(c) Pharmacy **delivery.**
(1) A per trip nonlabor cost of delivery of drugs is calculated by multiplying the estimated average mileage per trip by the Federal mileage allowance divided by the estimated average number of deliveries per trip.
(2) A per trip labor cost of delivery of drug is calculated by multiplying the estimated average travel time for each delivery by an average hourly salary rate for a delivery person based on direct and indirect costs.
(3) A per diem cost of delivery for each type of drug is calculated by adding the per trip nonlabor and labor costs and multiplying the result by the estimated number of trips per day for each type of drug.
(4) The per diem allowance for pharmacy delivery for each type of drug therapy is equal to the per diem cost of delivery for that type of drug therapy.

(d) **Nursing services and supplies.**
(1) A per visit cost for patient care time is calculated by multiplying the average number of hours spent with a patient in each visit by the average hourly salary for a nurse based on direct and indirect costs.
(2) A per visit cost for travel time is calculated by multiplying the average travel time per patient by the average hourly salary for a nurse based on direct and indirect costs.
(3) The per visit costs calculated in paragraphs (d)(1) and (d)(2) of this section are adjusted for area differences in wage levels by a factor (established by HCFA) reflecting the relative home health agency wage level in the geo-

graphic area of the home IV drug therapy provider compared to the nation average home health agency wage level.

(4) A per visit cost for travel is calculated by multiplying the estimated average mileage per visit by the Federal mileage allowance.

(5) A per visit cost of nursing supplies is calculated by adding the cost of supplies used in each visit.

(6) The per diem allowance for nursing services is calculated by adding the separate adjusted per visit cost for direct patient care time and travel time and the per visit costs for travel and nursing supplies and dividing by the average number of days between visits.

(e) Other equipment. The per diem allowance for other equipment is the separate per diem cost of the equipment not related to either pharmacy or nursing services calculated for each type of drug therapy by dividing the cost of the equipment necessary for the therapy by the average useful life of the equipment.

[Proposed actual amounts for all above services for 1990 were $45.44 per day for antibiotic therapy and $31.63 per day for pain management therapy.]

Calculation of Additional Allowances for Calendar Year 1990

(a) Patient education and counseling at the time IV drug therapy begins in the **home. The** amount of the allowance depends on whether the patient had begun IV drug therapy as a hospital inpatient.

(1) **Patient begins IV drug therapy while a hospital inpatient. If the** patient begins IV drug therapy as a hospital inpatient, the allowance is equal to two times the per visit cost for nursing services as a calculation by adding the per visit costs determined in 414.588 (d)(1) through (d)(4).

(2) Patient begins IV drug therapy outside the **hospital inpatient setting. If** the patient begins IV drug therapy in any setting other than that of a hospital inpatient, the allowance is equal to three times the per visit cost for nursing services as calculated by adding the per visit costs determined in 414.558 (d)(1) through (d)(4).

(b) Multiple IV drug regimen. A per diem allowance is made for the additional pharmacy services and supplies, nursing services, and other equipment needed for a patient who receives concurrently more than one IV drug. The per diem allowance is equal to the sum of the following:

(1) *50* percent of the applicable per diem allowance for pharmacy services as calculated in 414.558(a).

(2) 100 percent of the applicable per diem allowance for pharmacy supplies as calculated in 414.558(b).

(3) 100 percent of the applicable per diem allowance for other equipment & calculated in 414.558(e).

(c) Nursing services for initial dose of new drug **introduced into the drug regimen:**

(1) **Applicability. This allowance** is made for nursing services related to one nursing visit for the initial dose when a prescription change introduces an additional covered home IV drug to the patient's drug regimen or substitutes a new covered home IV drug for one already being used.

(2) Amount. This allowance is equal to 50 percent of the per visit costs for nursing services as calculated by adding the per visit costs determined in section 414.558 (d)(1) through (d)(4).

Calculation of Per Diem Fee Schedule and Additional Allowances for Calendar Years After 1990

The per diem fee schedule and additional allowances for calendar years after 1990 are periodically recalculated to take into account increases in costs of nursing and pharmacy services, supplies, and delivery, and other equipment.

Conditions of Participation for Home Intravenous Drug Therapy Providers (54 F.R. 37220)

This proposed rule sets forth the conditions of participation that an entity would be required to meet in order to qualify as a home intravenous drug therapy provider. This proposal would implement the provisions of section 1861 (jj)(3) of the Social Security Act, which was added by section 203(b) of the Medicare Catastrophic Coverage Act of 1988. An entity that meets these conditions of participation would be eligible for payment from Medicare for covered home IV drug therapy services furnished to Medicare beneficiaries.

Basis and Scope

This subpart sets forth the conditions that entities must meet to be approved for participation in Medicare as home IV drug therapy providers under section 1861(jj) of the Act and part 489 of this chapter.

Definitions

As used in this subpart unless the context indicates otherwise, "home intravenous (IV) drug therapy provider' "home IV provider" or "provider" means an entity that:

(a) Incapable of providing covered home IV drugs, nursing and pharmacy services, and other services as are necessary for the administration of home IV drug therapy; and

(b) Meets all the requirements of this subpart.

Condition of Participation; Compliance With Federal, State, and Local Laws

The home IV provider and all personnel who furnish services must be in compliance with applicable Federal, State, and local laws and regulations.

(a) **Standard: Compliance with Federal laws. The** home IV provider must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) Standard: Licensure **of home IV provider. If** State or local law requires licensing, the home IV provider must be currently licensed or approved as meeting the standards established for licensure.

(c) Standard: Licensure of personnel. Personnel who provide services, including individuals who provide services under arrangements with the home IV provider, must be licensed, registered, certified, or meet other applicable standards in accordance with applicable State and local laws.

Condition of Participation: Governing Body and Administration

(a) **Standard: Governing** body. A home IV provider must have either:
(1) A governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing all operations of the home IV provider; or
(2) Individuals who are legally responsible for the conduct of the home IV provider and who carry out the governing body functions that are specified in this section.

(b) Standard: Disclosure of ownership. The home IV provider must comply with the provisions of subpart C of part 420 of this chapter, which require health care providers and fiscal agents to disclose certain information about ownership and control.

(c) Miscellaneous reporting. The home IV provider must furnish information relevant to, and participate in, surveys and studies concerning cost-findings or other issues relating to the efficient administration of the home IV therapy benefit as requested by the Secretary under section 1861(jj)(3)(x) of the Act.

(d) Standard: Chief executive officer. The governing body must appoint a chief executive officer who meets the following conditions:
(1) Assumes responsibility for the overall management of the facility under the authority delegated by the governing body.
(2) Assumes responsibility for the day-to-day operation of the home IV provider.

(e) Standard: Patient care policies. The home IV provider must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:
(1) A description of the services furnished by the home IV provider's employees and those furnished under arrangements.
(2) The diagnostic criteria that identify the patients for whom the services are designed.
(3) Provisions for accepting only those patients whose needs can be met by the services it furnishes.
(4) Procedures for the acceptance of a referral, including the assignment of appropriate staff to conduct a timely assessment of the patient's medical and psychological readiness for home IV drug therapy services.
(5) Procedures for quickly notifying the referring physician if the patient does not meet the home IV provider's admission criteria.
(6) Procedures for notifying the referring physician of incidence of phlebitis, IV infiltration, or site infection that occurs after the provider begins furnishing home IV drug therapy services.

(f) Standard: Contracted services and professional management responsibility.
(1) The home IV provider must:
(i) Retain professional and administrative responsibility for and control and supervision of contracted services; and
(ii) Ensure that the services are furnished:
(A) In a safe and effective manner by nurses or pharmacists meeting the qualifications of this subpart; and
(B) In accordance with the patient's plan of care and other applicable requirements of this subpart.
(2) With each contractor that provides arranged services, the home IV provider must have a legally binding written agreement that meets at least the following requirements:
(i) Identifies the services to be provided.

(ii) Specifies that contracted services are provided only if directly authorized by the home IV provider.

(iii) Describes the manner in which the contracted services are coordinated, supervised, and evaluated by the home IV provider.

(iv) Delineates the roles of the home IV provider and the contractor in the patient care process.

(v) Provides for the preparation of patient records with progress notes and observations and for the prompt incorporation of the patient records into the clinical record of the home IV provider.

(vi) Provides that the requirements for the services furnished under arrangements and personnel who furnish them are the same as for the services furnished directly by the home IV provider and the personnel who furnish them.

(vii) Specifies the financial arrangements that provide for payment to the contractor by the home IV provider for the provision of covered services.

(viii) Specifies that a contractor that furnishes services under arrangements may not bill the patient or Medicare for covered services.

Condition of Participation: Patient Selection

After a patient's referring physician requests home IV drug therapy, the home provider makes an assessment of each patient and his or her needs. For hospital inpatients, the home IV provider must make this assessment prior to discharge. The home IV provider furnishes services only to patients whose needs can be met by its services.

(a) Standard: Medical criteria. A patient must:

(1) Be under the care of a licensed referring physician who either prescribed the home IV drug or established the plan of care, or both, and who continually monitors the home IV drug therapy;

(2) Have a clinical status that allows IV drugs to be safely administered in the home;

(3) Have venous sites available for peripheral IV catheter or needle placement or have a central venous catheter or other central venous access device; and

(4) Be unable, for medical or therapeutic reasons, to take the provided medication orally or by other means less intrusive than IV.

(b) Standard: Nonmedical criteria. A patient must:

(1) Be capable of performing safely self-administration of drugs and self care after adequate patient education (for example, be able to learn aseptic technique and heparin lock maintenance and read and understand the labeling of the home IV drugs) or have a primary care giver who can perform these tasks;

(2) Be motivated to use home IV drug therapy services;

(3) Be psychologically stable (that is, the prospect for adherence to a disciplined medical regimen is realistic); and

(4) Have a home environment that is conducive to the provision of home IV drug therapy services (that is, a clean home with electricity, a telephone, running water, refrigeration, and enough space to support home IV drug therapy services).

Condition of Participation: Plan of Care

For each patient, the referring physician must establish and periodically review a plan of care.

(a) Standard: Development of the plan of care. A plan of care must meet the following requirements:

(1) The **plan** of care is developed by the patient's referring physician.

(2) The plan of care is implemented by the home IV provider.

(3) The plan of care is based on the referring physician's initial and ongoing individual patient assessments.

(4) The plan of care is reviewed by the referring physician as necessary, but at least once every 30 days.

(5) The plan of care includes at least the following current information about the patient and the home IV drug therapy services to be provided:

(i) **The patient's name, gender, age, and lean body weight.**

(ii) **A narrative description of the appropriate diagnoses.**

(iii) **The patient's drug allergies or sensitivities.**

(iv) **The patient's current drug therapy, including nonprescription drugs, and home remedies.**

(v) **The goal of the provision of home IV drug therapy services for the patient.**

(vi) **The drugs and method of drug therapy administration to be furnished by the home IV provider including:**

(A) **Amount** of dosage and timing of administration;

(B) Route of administration, either peripheral or central venous line.

(c) Frequency of IV site monitoring; and

(D) Type of IV equipment, related sup-

plies and other equipment, and fluids to be administered.

(vii) Identifying physician information, the physician's signature, and the date.

(b) Standard: Referring physician review of plan or care. The referring physician review of the plan of care must meet the following requirements:

(1) The referring physician reviews the patient's process in attaining the objectives of the plan of care at least every 30 days.

(2) The review is based upon appropriate information provided by health professionals, including information furnished by the registered nurse and pharmacist employed by the home IV provider.

Condition of Participation: Central Clinical Records

In accordance with accepted principles of practice, the home IV provider must establish and maintain a clinical record for all individuals receiving care and services including those who are not entitled to Medicare. Each clinical record must be completely, promptly, and accurately documented, readily accessible, and systematically organized to ease retrieval and compilation of information.

(a) **Standard: Content.** Each clinical record is a comprehensive compilation of information of medical and other data that must contain sufficient information to identify the patient clearly and to justify the diagnosis treatment. Entries in the clinical record must be made for all services provided directly or under arrangements. Entries must be made for each treatment performed and must be signed by the individual who performs the services. Documentation on each patient must be consolidated into one clinical record that must contain the following information:

(1) Patient identification data.
(2) The initial patient assessment and subsequent reassessments.
(3) Current plan of treatment.
(4) Consent and authorization forms.
(5) Past and present pertinent medical history.
(8) Complete documentation of all services provided.
(7) Upon completion of treatment, a summary that includes a-description of patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) **Standard: Retention and preservation. The** home IV provider must retain-clinical records for the appropriate time period as specified in this paragraph. If the requirements of State law are used to define the time period for maintaining clinical records, it must be the law of the State in which the services were provided to the patient.

(1) If the State where the services are furnished has a law that applies to the provider governing the maintenance of clinical records, the home IV provider must maintain its clinical records for the time required by that law.

(2) In the absence of an applicable State law, the home IV provider must maintain clinical records for the time periods provided under the appropriate statute of limitations concerning medical malpractice in the State.

(3) If there is no applicable State law or State statute of limitations concerning medical malpractice, the home IV provider must maintain clinical records for at least 5 years.

(4) In addition, for services furnished to a minor, the home IV provider must maintain clinical records for at least 3 years after the individual attains the age of majority under State law.

(c) Standard: Protection of information. The home IV provider must-

(l)- Safeguard the clinical record against loss, destruction, or unauthorized use;

(2) Have procedures to govern the use and removal-of records, to ensure release of information only to authorized individuals, and to ensure that unauthorized individuals cannot gain access to, or alter, patient records;

(3) Obtain the patient's written consent before releasing information not required to be released by law; and

(4) Release original records only in accordance with Federal or State Laws, court orders, or subpeoneas.

(d) Standard: Patient access. The home IV provider must permit each patient of his or her legal representative to inspector obtain copies of his or her clinical records within 48 working hours after the provider receives a written request.

Condition of Participation Core Staff, Core Services, and Full-time Availability of Patient Core Services

A home IV provider must make all necessary nursing and pharmaceutical services available 24 hours a day, 7 days a week to meet the reasonable needs of its patients with respect to home IV drug therapy services.

(a) Standard: Core staffing requirements. A home IV provider must employ directly either a full-time registered nurse or a full-time register pharmacist.

(b) Core services. A home IV provider must perform the following oversight and supervisory functions itself (that is, these function may not be furnished under arrangements);

(1) Assurance that all patient care related nursing and pharmacy services, whether furnished directly or under arrangements, are available on a 24-hour-a-day, 7-day-a-week basis.
(2) Development and coordination of all activities of nurses and pharmacists including assuring that only qualified, properly trained individuals furnish these services.
(3) Necessary consultations and coordination concerning a patient's plan of care with the patient's physician and provision of all patient laboratory test results.
(4) Conduction a quality assessment and assurance program including drug regime review.

(c) **Standard: 24-hour availability of patient care services.**
(1) To meet the needs of patients, a home IV provider may contract for additional nursing or pharmacy services to supplement the services directly furnished by the home IV provider. If services directly furnished under arrangement [sic], the provider must maintain professional, financial: and administrative responsibility for the services.
(2) A home IV provider must be able to meet the following time requirements related to care of a patient:
(i) The home IV provider must make routine or urgently needed nursing, pharmacy, and related services and home IV drugs and supplies available 24 hours a day, 7 days a week.
(ii) The home IV provider must be accessible to patients at all times. If a patient or caregiver telephones the home IV provider with a problem concerning the administration of a drug or malfunctioning equipment, the provider must be able to make telephone contact with the patient or caregiver within 10 minutes, and the provider must be able to resolve that problem as expeditiously as possible given the nature of the problem.
(iii) In an emergency, the provider must be able to deliver drugs to the patient at least 30 minutes before the drugs are scheduled for use.
(iv) The home IV provider must furnish services in a manner consistent with accepted standards of medical practice.

Condition of Participation: Nursing Services

(a) **General requirements. The** home IV provider is responsible for furnishing nursing services, directly or under arrangements, that are necessary for the provision of IV drug therapy services. Persons furnishing the nursing services either as employees of the home IV provider or of the organization under contract with the home IV provider must be either registered nurses, or in States that permit such practice, physicians or physicians assistants under the supervision of a physician. (In such States, the references in this subpart to a "registered nurse" or "nurse" are read to include physician assistants.) In addition, the home IV provider must:
(1) Direct and staff nursing services to ensure that the needs of its patients are met;
(2) Specify the patient care responsibilities of the nurses; and
(3) Ensure that the requirements of paragraphs (b) through (d) of this section are met.

(b) **Education and experience.**
(1) The home IV provider must ensure that each nurse who furnished home IV drug therapy services meets the following requirements for education. experience, and proficiency:
(i) Education in the principles and practices of infusion therapy and cardiopulmonary resuscitation.
(ii) Experience in patient assessment and infusion therapy.
(iii) Proficiency in all clinical aspects of IV therapy with validated competency in clinical judgment and practice demonstrated by work experiences. For example, each nurse must be able to access peripheral veins and must be able to recognize medication and solution incompatibilities.
(iv) Ability to perform the following procedures:
(A) **Interpret the physician's order for IV therapy and administer IV medications as ordered.**
(B) **Perform venipuncture and insertion of all types of needles and catheters commercially available (excluding the insertion of subclavian, jugular, and cut-down catheters).**
(c) **Prepare IV solutions with the addition of medications in the absence of admixture services.**
(D) **Initiate, monitor, and terminate IV solutions and additives.**
(E) **Evaluate the effectiveness of the dosage, frequency, and route of administration of IV drugs and the patient's adherence to the drug regimen.**
(F) **Set the flow rates established by the physician for all IV solutions and medications.**

(G) Maintain and replace sites, tubing, and dressing in accordance with established policy.

(H) Draw blood.

(v) Thorough knowledge of and proficient technical ability in the use of the specific type of IV equipment to be used by a particular patient so that the nurse is able to evaluate IV equipment and identify when maintenance would be necessary.

(vi) Ability to observe and assess all significant reactions related to IV therapy and initiate appropriate nursing interventions.

(c) Aseptic practices. Each nurse must follow established infection control and aseptic practices.

(d) Physician notification. All significant findings of the nurse in the course of delivering home IV services must be communicated to the physician.

(e) Documentation. Each nurse must document in the patient's clinical record his or her action associated with the preparation, administration, and termination of all aspects of IV therapy.

Condition of Participation: Pharmacy Services

The home IV provider must ensure that a registered pharmacist is responsible for purchasing, preparation, safe administration, and clinical monitoring of drugs. The home IV provider may directly furnish necessary pharmacy services or it may enter into arrangements for the services.

(a) **Standard: Pharmacy services management. The** home IV provider must ensure that necessary pharmacy services, furnished directly or under arrangements, are furnished in accordance with the following requirements:

(1) The policies and procedures of the home IV provider must ensure that pharmacy practice at all times is consistent with applicable law and regulations governing professional licensure and operation of pharmacies.

(2) The home IV provider must maintain and make available an up-to-date copy of HCFA's list of covered home IV drugs and pharmaceutical references **that** include official pharmaceutical practice as it relates to patient care.

(3) The home IV provider must maintain patient profiles that include:

(i) The patient's name, age, and lean body weight;

(ii) The patient's diagnosis or diagnoses;

(iii) Clinical information relating to the patient's initial and ongoing home IV drug therapy;

(iv) Current drug therapy provided to the patient including nonprescription and home remedy products; and

(v) A description of the patient's drug allergies or sensitivities.

(4) A pharmacist reviews each prescription order before dispensing a drug to ensure that the drug is a covered home IV drug and that the correct drug is dispensed to the patient.

(5) A pharmacist assists the physician in determining the appropriate schedule for monitoring the patient through laboratory testing. This schedule must include identification of tests to be performed and the Medicare-approved laboratory that will perform the tests and frequency of testing and obtaining the results.

(6) A pharmacist supervises support personnel to ensure adequate quality of the drugs and pharmaceutical supplies.

(b) Standard: Storage, equipment, and preparation area.

(1) The IV provider must ensure that drugs, supplies, and equipment are maintained in the pharmacy in accordance with the following procedures:

(i) Drugs must be stored separately under proper conditions of sanitation, temperature, light, moisture, ventilation, and security.

(ii) Areas used in the preparation of sterile products must be constructed **to minimize** opportunities for particulate and microbial contaminations and must be separate from areas used in preparation of nonsterile products.

(iii) Work surfaces are kept free of equipment, supplies, records, and labels unrelated **to the** preparation of **a** given prescription.

(iv) Work surfaces and equipment must be disinfected after the preparation of each prescription.

(v) Clean work benches or laminar flow hoods **must be used in the preparation of IV drugs and must be inspected at least annually in accordance with standard inspection practice.**

(vi) **Both ingredients and final products must be inspected for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination. The equipment necessary for such an inspection must be maintained by the pharmacy.**

(vii) Drugs must be kept in a locked storage area.

(vii) Each dosage unit of both a cytotoxic drug and a Schedule II controlled drug

must be accounted for in a distribution log.

(2) Unless contraindicated, an appropriate air-eliminating filter must be employed in the home for delivery of IV fluids.

(3) Mislabeled or otherwise unusable drugs must not be made available for patient use.

(4) Outdated drugs must be destroyed.

(c) **Standard: Drug labeling. The** label on any IV drug or solution that has been dispensed to a patient must contain at least the following information:

(1) The name, address, and telephone number for the pharmacy and the telephone number of the home IV provider if the pharmacy services are furnished under arrangements.

(2) The dates of both preparation and expiration of the drug.

(3) The pharmacy's identifying serial number for the drug order or prescription.

(4) The full name of both the patient and prescribing physician.

(5) The name of the drug, its strength, and the amount dispensed.

(6) The directions for use including the scheduled date, time, and rate of administration, and appropriate space for the patient or caregiver to add the date and time the solution is started. These directions must indicate that the IV fluids must be completely used or discarded within 24 hours of mixing or unfreezing a mixture.

(7) The directions for storage.

(8) Cautionary or accessory labels if appropriate.

(9) The lot number or control number of the batch from which the drug was obtained.

Condition of Participation: Patient and Caregiver Evaluations and Instructions

To ensure safe home IV therapy for the patient, a registered nurse who is proficient in the delivery of home IV drug therapy services evaluates the patient to determine suitability for the provision of home IV drug therapy services. If the nurse determines that the patient is suitable for this therapy and the home IV provider can furnish the necessary therapy, the nurse trains the patient or caregiver or both, as appropriate, in providing the therapy and in proper maintenance of the equipment.

(a) Standard: Patient evaluation. The registered nurse performs the following activities:

(1) Reviews the referring physician's medical orders before evaluating a patient for home IV drug therapy.

(2) Before accepting the patient for care, evaluates the patient or caregiver for general competency and specific comprehension of the particular IV drug therapeutic procedures to be used. In making this evaluation, the nurse:

(i) Discusses possible complications of the treatment with the patient or caregiver or both as appropriate.

(ii) Explains and demonstrates home IV drug therapy procedures to the patient or caregiver.

(iii) After the patient or caregiver demonstrates IV drug therapy procedures, including aseptic techniques, evaluates and documents the competency and proficiency of the patient or caregiver.

(3) May inspect the patient's home prior to hospital discharge to ascertain that there is an area in the home available for storage of drugs and supplies and an area available for use of sterile supplies.

(4) Supervises the patient or caregiver when either starts the first infusion therapy at home to verify his or her ability to transfer learning from the provider setting to the home setting.

(b) **Standard: Patient and caregiver education and instructions. The** nurse instructs the patient or caregiver, as appropriate, in home IV drug therapy procedures, including aseptic techniques and provides written and illustrated instructions.

(1) The written instructions that are prepared for each different drug class and administration route must include the following information:

(i) A step-by-step description of the procedures that the patient or caregiver must follow in administering an IV drug, including procedures for any probable emergency that might arise.

(ii) Storage procedures.

(iii) Procedures for disposal of drugs and IV equipment.

(iv) A telephone number that would enable a patient to receive assistance at any time.

(2) The nurse must instruct the patient or caregiver about the following:

"(i) Methods of detecting early signs and symptoms of IV-related sepsis and complications so that they may be reported immediately to the home IV provider's medical personnel.

(ii) When appropriate, use of electronic controlling devices (for example, an infusion pump) in delivery of home IV drug therapy so that the patient or caregiver can recognize any malfunction that should be reported to the home IV provider.

(iii) Emergency interventions for possible IV

complications that can be performed by the patient or caregiver.

(iv) Discarding IV needles in an appropriate receptacle (such as a Sharp's container) that is properly labeled and that is removed by the home IV provider staff or personnel at least every 3 days.

(v) Procedures for recording the administration of IV solutions and drugs so the information can be given to the home IV provider and attached to the patient's clinical record.

(3) The nurse must discuss the range of physical activity that is appropriate for the patient.

Condition of Participation: Protocols and Policies

The home IV provider adheres to the following procedures and has written protocols and policies consistent with respect to the provision of home IV drug therapy items and services.

(a) Standard: First dose. The first dose of any drug not previously administered intravenously is administered under the direct supervision of a physician or nurse who must:

(1) remain in attendance for a time period sufficient to make sure that the patient is stable; and

(2) Have resuscitation medication and equipment to treat anaphylaxis readily available.

(b) Standard: Venipuncture and catheter care.

(1) The site of a peripheral catheter is rotated by the nurse at least every 3 days. A catheter whose tip lies in a central vessel must be rotated by a physician when appropriate.

(2) IV administration sets are changed at least every 24 hours by the patient or caregiver.

(3) IV dressings should be changed at least every 48 hours or immediately upon becoming soiled or wet.

(4) The air elimination filter is routinely changed.

(5) The central line catheter site is inspected by a nurse at least once each week

(6) Aseptic techniques are practiced during all venipuncture, dressing changes, catheter care, and assembly of IV infusion systems.

(c) Standard: Quality of the air elimination filter and sterility of the catheter.

(1) On a sample of patients, the nurse packages air elimination filters that have been removed by the nurse from the IV tubing and immediately sends then to an independent laboratory for analysis of particulate matter and bacterial and fungal contamination.

(2) On a sample basis, the home IV provider packages catheters that have been removed from patients and immediately sends them to an independent laboratory for analysis of sterility.

(3) The home IV provider keeps copies of laboratory results on the testing of both air elimination filters and catheters that are made available for review upon request.

(d) **Standard: Drug therapy review.**

(1) The pharmacist and nurse must review the combination of IV drugs and equipment for appropriateness before drug therapy is initiated.

(2) The pharmacist must conduct ongoing review (at least once every ***3*** days) of the drug therapy and inform the physician of significant findings. As a minimum, this review must include the appropriateness of the drug regimen and any instances of therapeutic duplication of drugs.

(e) **Standard: Patient rights and responsibilities. The** home IV provider must ensure that the following requirements are met:

(1) Treatment of a patient begins only if the home IV provider is capable of furnishing needed care at the level of intensity required by the condition of the patient.

(2) Each patient receives care appropriate to his or her needs in a timely manner.

(3) The patient is informed in a timely manner of the need for transfer to another medical entity or level of care and of any appropriate alternatives.

(4) If the home IV drug therapy is to end without transfer to another medical entity, the patient is informed in a timely manner of the impending discharge, continuing care requirements and other available services, if needed.

(5) Patients' rights as set forth in this paragraph are honored and patients are informed of their responsibilities, if any, in the care process. The rights and responsibilities are clearly stated in documents distributed to patients upon admission to the home IV drug therapy program.

(6) Procedures are established to deal with patient grievances and patient-recommended changes without coercion, discrimination, reprisal, or interruption of services. A patient is informed at the beginning of home IV drug therapy about these procedures for making, reviewing, and resolving complaints.

(f) **Standard: Written protocols and policies. The** home IV provider has written protocols and policies that are consistent with these procedures.

Condition of Participation: Quality Assurance

The home IV provider maintains an ongoing quality assurance program designed to monitor patient care objectively and systematically, evaluate the quality and appropriateness of patient care, resolve identified problems, and pursue other opportunities to improve patient care, resolve identified problems, and pursue other opportunities to improve patient care.

(a) Standard: Program **objectives.** Through an ongoing, planned, and systematic process, the home IV provider monitors and evaluates the quality and appropriateness of patient care, including the performance of employees and other personnel who furnish services under arrangements with the home IV provider. The home IV provider includes at least the following in a written evaluation plan:
  (1) Scope and objectives of the quality assurance activities.
  (2) Activities identified for monitoring and evaluation.
  (3) Methods for implementing the monitoring and evaluation activities and for reporting the results.
  (4) Mechanisms for taking follow-up action.
  (5) Staff responsibilities for each activity in the quality assurance program.

(b) Standard: Patient care.
  (1) The monitoring and evaluation of the quality and appropriateness of patient care by the home IV provider must include identification of important aspects of care or service and focus on high-risk high-volume, or problem-prone activities.
  (2) The home IV provider collects data about the following matters:
    (i) Length of home IV drug therapy by diagnosis and treatment.
    (ii) Incidence and causes of patient rehospitalization.
    (iii) Incidence of:
      (A) Phlebitis;
      (B) Infiltration;
      (C) Site infection; and
      (D) Other infection.
    (iv) Hydration and nutritional status.
  (3) The home IV provider analyzes the data it collects at least annually to determine the frequency of negative outcomes and prescribes corrective action for negative outcomes.

(c) Standard: Service delivery. The provider determines the following:
  (1) Drugs and IV equipment were delivered timely to the patient.
  (2) The patient could read the preparation and expiration dates on the drug labels.
  (3) A nurse visited a patient with a peripheral IV catheter placement every 3 days and rotated the peripheral IV injection site.
  (4) A nurse visited any patient with a central line at appropriate intervals for monitoring.
  (5) Procedures have been established to enable patients to make complaints.
  (6) The provider found acceptable solutions for complaints and kept a record of both.

Condition of Participation: Infection Control

The home IV provider must develop infection control procedures. These procedures must address at least staff personal hygiene and health status, isolation precautions, aseptic procedures, cleaning and sterilization of equipment, and methods to avoid transmitting infections. The home IV provider:

(a) Advises staff, patients, and caregivers of any necessary precautions, including infection control and personal hygiene and their responsibilities in the infection control program; and

(b) Develops a system for evaluating, reporting, and maintaining records of infection related to the care of service provided among patients and as appropriate, among staff.

Appendix D

A BASIC ECONOMIC MODEL OF HOME DRUG INFUSION PROVIDER BEHAVIOR[1]

Basic economic models of health provider behavior have been applied to hospitals, physicians, nursing homes, and home health agencies. The models are of two types: 1) those that assume that providers are profit maximizing, and 2) models of behavior of not-for profit organizations.

The first type of model has been applied to both for-profit and not-for-profit organizations, where it is assumed that not-for-profit providers face essentially the same financial incentives as for-profit providers operating in the same markets. Models of the second type (see, e.g., references 89,175,244,258) incorporate some specific factors thought to affect behavior of not-for-profit organizations. These include the possible desire of managers to maximize size or prestige of their organization or to satisfy the desires of special interest groups. These objectives, in turn, may imply that not-for-profit organizations pay more attention to volume of services, quality, or their reputation for community service than for-profit organizations.

The critical issue here, however, is whether there are differences in the way for-profit and not-for-profit organizations respond to incentives created by alternative payment methods. This appendix will later discuss some possible differences, but it assumes thereto be substantial similarities in the responses of for-profit and not-for-profit organizations; similar interests in the financial viability of the organization transcend differences in form of control. For both types of organizations the principal determinants of the quantity, cost, and quality of services include:

- the cost of inputs,
- the technology of production,
- the demand for services by patients, and
- the level and form of public and private payment for services.

Assumptions

A model must be based on some assumptions about provider behavior and the cost structure. This model begins with an assumption that providers are profit maximizers, or behave much like profit maximizers subject to some constraints to be specified. It later notes differences where they may be important.

The model presumes that providers incur some fixed costs (e.g. administrative overhead) and have a constant or near-constant marginal cost for services (for equipment, supplies, and labor). These assumptions are reasonable for home drug infusion therapy providers since most such providers can hire staff locally without significantly driving up the market price. Most such providers probably employ a small share of the suitable employees locally and represent a small share of the national market for supplies. Limited short-run supply of staff in small market areas may, nonetheless, lead to an upward-sloping marginal cost curve for some providers.

The model presumes that providers serve both Medicare and nonMedicare patients. It also presumes that, except in cases of patient cost sharing (deductibles and copayments), the demand of Medicare patients is independent of prices charged, but that at least some other patients (self payers or those with insurance involving cost sharing) are sensitive to prices. So the demand of Medicare patients is perfectly price inelastic and providers face a downward sloping demand curve for services provided to other patients.

Provider Behavior Under Different Forms of Reimbursement

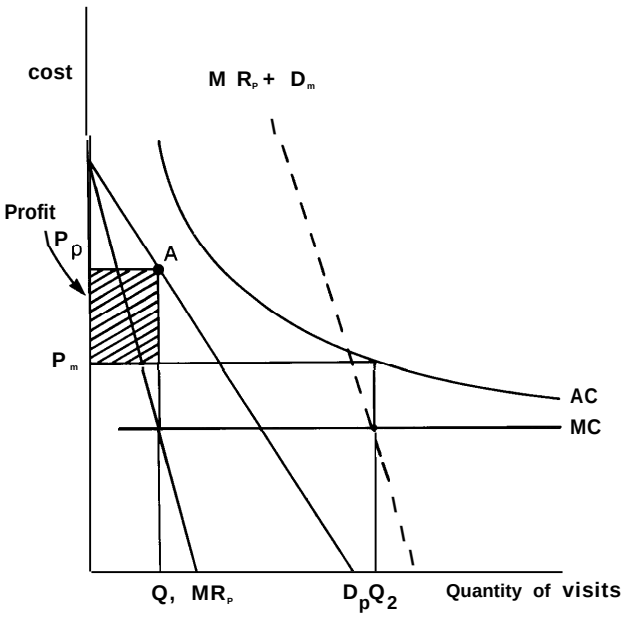
Figure D-1 illustrates profit maximization under cost reimbursement. The demand of private-pay patients is Dp and the associated marginal revenue curve is MRp. The provider's average cost curve is AC. This cost curve should be viewed as endogenous-costs could be higher or lower, depending on visit quality and provider efficiency. Pp and Pm represent payment levels from private patients and Medicare, respectively.

In this mode1[2] the provider maximizes profits by setting marginal revenue equal to marginal cost, where the marginal revenue curve is detemined by the (horizontal) sum of the private patient marginal revenue curve and the demand of Medicare beneficiaries (MRp + Din). At point A in figure D-1 the provider supplies Q_1 **units** of service **to private-pa, patients and Q_2-Q_1 units to Medicare**

[1] **This appendix is based on T. Grannemann, "Incentives and Behavioral Response to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program,' paper prepared** under contract to the **Office** of **Technology** Assessment, Washington DC, February 1990.

[2] See reference 111 for basic models of provider behavior, or reference 254 for a similar model of provider response to limited Medicaid payment rates.

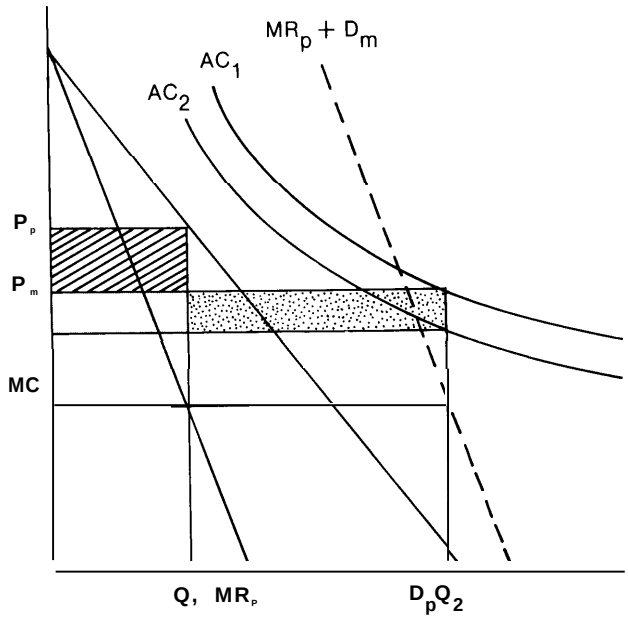
Figure D-l—Home Drug Infusion Therapy Provider Behavior: Profit Maximization Under Cost Reimbursement



NOTE: See text for explanation.

SOURCE: T. Grannemann, "Incentives and Behavioral Responses to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program," paper prepared under contract to the Office of Technology Assessment, Washington, DC, February 1990.

Figure D-2—Home Drug Infusion Therapy Provider Behavior: Profit Maximization Under Prospective Payment



NOTE: See text for explanation.

SOURCE: T. Grannemann, "Incentives and Behavioral Responses to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program," paper prepared under contract to the Office of Technology Assessment, Washington, DC, February 1990.

patients. The profit (or surplus for not-for-profit providers) is shown in the shaded area.

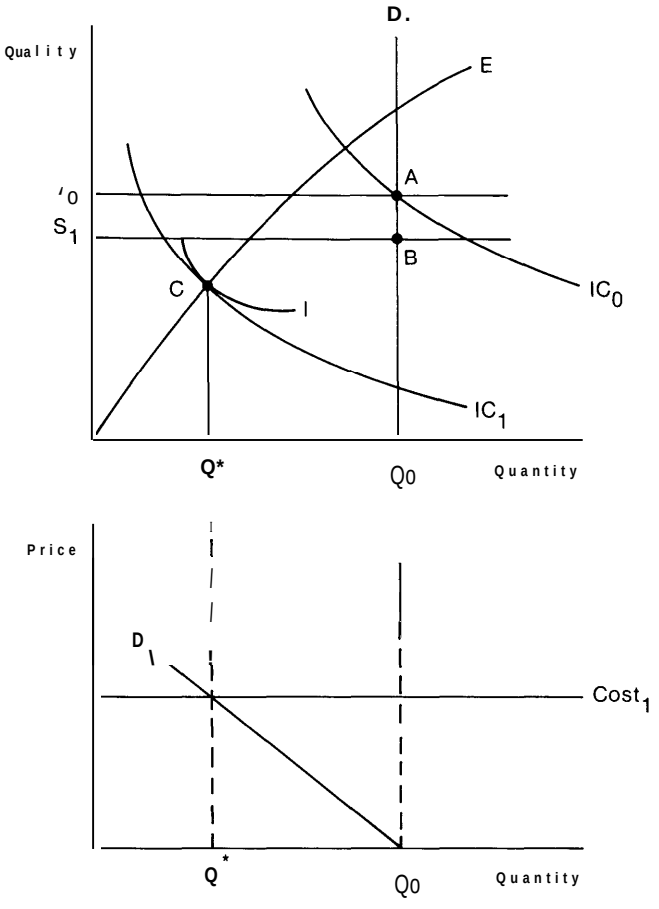
Prospective payment, that is, where providers receive a predetermined, fixed rate of payment, provides strong incentives to control costs. In figure D-2, under cost reimbursement the only gain to the provider from reducing average cost from AC_1 to AC_2 is the dark area. But under prospective payment, the provider could keep the dotted area as profits as well, thus providing extra incentive to reduce costs. A shift from cost reimbursement to prospective payment in such circumstances could give providers a short-run windfall gain in profit or surplus and could provide Medicare with an opportunity to lower per unit payments below the initial level of Pm. Profit-seeking providers might be the most responsive to such incentives, while not-for-profit organizations may be less interested in additional surplus than in maintaining high quality at the higher cost. The choices for not-for-profit organizations nonetheless are expanded by prospective payment, as they are given an opportunity to use any savings derived from reduced costs for other purposes, such as covering care for the poor or providing other services needed in the community.

Impacts on Quality of Care

Like quantity, the level of quality a provider chooses to produce can be viewed as a product of supply and demand. Fully insured patients who have no cost-sharing requirements can be expected to demand the highest level of quality, to the point where extra quality provides no additional benefit (after accounting for any cost in terms of patient inconvenience). Cost-reimbursed providers have every reason to be accommodating to these patient desires. Providers may, however, provide a uniform standard of care to all their patients. So a provider's quality standards may reflect the best possible accommodation to all patients, insured and uninsured.

The provider's choice of quantity and quality of visits is illustrated in figure D-3. This figure shows possible combinations of quality and quantity. The iso-cost (IC) curves represent combinations of quality and quantity that can be attained at a given cost. The Engle curve (E) represents the patient's preferred combinations of quality and quantity, given the relative costs of producing each. This curve is determined by the point of tangency of indifference curves with iso-cost curves.

Figure D-3—Provider Tradeoffs Between Quality and Quantity of Visits Under Alternative Payment Methods



NOTE: See text for explanation.

SOURCE: T. Grannemann, "Incentives and Behavioral Responses to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program," paper prepared under contract to the Office of Technology Assessment, Washington, DC, February 1990.

Point A represents ***cost reimbursement in*** which the patient demands and receives Qo visits-the amount demanded at zero out-of-pocket cost, shown in the lower portion of the figure. The quality of visits, determined by the provider's standard of care, S, is directly related to the cost curve discussed above. Lower costs imply lower quality, though more efficient providers may have lower costs without sacrificing quality.

Point B in figure D-3 represents the likely result of ***per-visit prospective payment*** that covers at least marginal cost. The provider has incentives to keep costs lower than with cost reimbursement and may provide services of somewhat lower quality. But the provider has no reason to deviate from the patient's desired quantity of care, Qo-since the provider continues to make a profit on each unit of service.

Point C represents the possible outcome of ***per-month or per-episode prospective payment.*** Providers would maximize profits by keeping costs as low as possible subject to the need to maintain patient satisfaction sufficient to maintain a suitable patient load. Professional standards, or quality assurance standards imposed by Medicare, must also be met. Profits can be expressed as:

Profit = N(quality, quantity) * payment - cost(quality, quantity)

First order conditions for profit maximization require that the marginal contribution of quality and quantity to number of patients (N) weighted by the payment rate just equals their respective marginal contribution to cost.

To maximize profits, then, providers must operate where the marginal cost due to increased quality (quantity) just equals the marginal benefit in terms of patients added due to a quality (quantity) increase. Providers thus must be responsive to patient preferences regarding quality and quantity mix. It is likely, therefore, that providers under per-month or per-episode prospective payment will operate close to the Engle curve in figure D-3 and on an iso-cost curve lower than would be the case under cost reimbursement or per-visit prospective payment. If, as shown by point C and the lower portion of figure D-3, competitive forces lead to a point on the Engle curve where the quantity equals what would be demanded by an uninsured patient, then an optimal quantity and quality would also be achieved in the sense that marginal cost equals marginal benefit to the patient. One would therefore expect per-month or per-episode prospective payment to lead to lower quality and fewer visits per week than would be found under cost reimbursement.

While incentives would lead providers in this direction, competitive forces and quality assurance regulations could counterbalance this effect. If policymakers desire higher quality and frequency of visits than competitive forces and professional standards can sustain, then regulations or other quality assurance systems must be established.

To summarize the implications of this model:

- Cost reimbursement promotes high quality care with incentives for providers to meet any patient demands for quantity (frequency) of service.
- Per-visit prospective rates promote cost control and lower quality, without any incentive to reduce quantity (frequency) of visits.
- Per-month or per-episode prospective payments encourage both cost control and reduction in quantity or frequency of visits.

. Quality assurance mechanisms or regulatory controls may be used to counter some of the adverse effects of incentives under prospective payment. Under per-visit rates, controls may be needed on quality but not frequency of visits. Under per-month or per-episode rates, controls maybe needed on both quality and frequency of visits.

Appendix E
GLOSSARY OF TERMS

Access: Potential and actual entry of a population into the health care delivery system.

Acute care: Services within a hospital setting intended to maintain patients for medical and surgical episodic care over a relatively short period of time.

Acute disorder: Characterized by a sudden onset, marked symptoms, and a short course.

Analgesic drug: A substance causing loss of sensitivity to pain without loss of consciousness.

Anaphylaxis: An unusual or exaggerated allergic reaction to foreign proteins or other substances.

Anemia: An abnormal decrease in the concentration of erythrocytes (red blood cells), concentration of hemoglobin, or hematocrit.

Antibiotic drug: Any of a number of substances produced by one microorganism and inhibitory to another microorganism.

Antineoplastic drug: Substance acting against the formation of a tumor.

Artery: A blood vessel that carries the blood away from the heart to the various parts of the body.

Aseptic: Free from infection.

Average cost: For a home infusion provider, ***average total cost*** per patient is the sum of all the provider's costs of providing services, divided by the number of patients served. Of total costs, some costs are fixed in the short run (e.g., capital equipment), while others vary depending on the number of patients served (e.g., dressing supplies). ***Average variable costs are the*** sum of these variable costs, divided by the number of patients served. In the long run, average variable costs may approximate ***marginal costs.***

Catheter: In infusion therapy, the tube that is inserted into the body (e.g., into a vein) so that drugs or other fluids can be administered.

Cellulitis: Infection of the skin and surrounding soft tissue.

Central access device: An infusion device in which the catheter is inserted directly into a large vein near the heart.

Chronic disorder: A disorder characterized by extended duration and typically by slow development or a pattern of recurrence.

Conditions of participation: Requirements that a hospital or other health care facility must meet in order to be allowed to receive payments for Medicare patients. An example is the requirement that hospitals conduct utilization review.

Cystic fibrosis: A genetic disorder that results in abnormal mucous secretions, including excess mucus in the lungs. Persons with cystic fibrosis are predisposed to recurrent pulmonary infections.

Cytotoxic drug: A drug that has a specific toxic action upon cells or special organs.

Diagnosis-related groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are the case-mix measure mandated for Medicare's prospective hospital payment system by the Social Security Amendments of 1983 (Public Law 98-21).

Dialysis: In persons with end-stage renal disease, a process that rids the body of liquid waste products, replacing the kidney's normal function.

Drug regimen: A systematic plan for taking medication that is designed to improve or maintain the health of a patient.

Durable medical equipment: Medical equipment that is capable of withstanding repeated use, generally not useful to someone in the absence of injury or illness, and appropriate for home use. Examples include intravenous poles and infusion pumps.

Elastomeric infuser: An infusion device that consists of a disposable container with an inner elastic bladder that can be filled with medication.

Embolus: A detached blood clot, air bubble, or clump of foreign matter that blocks or occludes a blood vessel.

Enteral nutrition: The intake of nutrients that undergo at least partial processing in the intestine. Strictly speaking, enteral nutrition includes normal food intake through the mouth. However, the term is often used to indicate more specifically the intake of nutrients through a tube that leads directly to the stomach or the small intestine.

Epidural drug administration: Entrance of a drug into epidural space surrounding the spinal cord, so that the drug is absorbed directly into the spinal cord.

Extravasation: The forcing out of fluid (e.g., an infused drug) from a proper vessel into the surrounding tissue.

Family caregiver: A family member or friend who assists the patient in self-care responsibilities on an unpaid basis.

Febrile: Of or pertaining to fever.

Fiscal intermediary: An organization that acts as an agent and purchaser of health care insurance or health care services for an insurer. Medicare's fiscal intermediaries include Part A intermediaries and Part B carriers (see ***Medicare intermediaries or carriers).***

Granulocyte: A leukocyte (white blood cell) that contains granules in its cytoplasm.

Gravity drip system: A drug delivery system in which a bag or bottle is hung on a hook or a pole above the level

of the patient, and fluid flows by gravity down the line and into the catheter. The rate of flow in a simple gravity drip system is controlled primarily by a special clamp or valve on the line that can be adjusted to permit the prescribed amount of fluid to flow through.

Health maintenance organization: A health care organization that, in return for prospective per capita payments, acts as both insurer and provider of comprehensive but specified medical services.

Hemolytic reaction: A process by which erythrocytes (red blood cells) are destroyed.

Hemophilia: An inherited disease in which the body lacks blood coagulation (clotting) factors.

Heparin: An anticoagulant drug.

Homebound: Confined to the home.

Home drug infusion therapy: Treatment that consists of prolonged (or continuous) injections of drugs that are administered in the home, usually repeatedly.

Home health agency: An organization that delivers health services to patients in the home setting.

Hospice: A facility or program designed to provide a caring environment for supplying the physical and emotional needs of the terminally ill.

Immune globulin: A biological preparation that consists of proteins from human blood plasma. These proteins react with foreign proteins to form antibodies that aid in the body's defense against infections.

Immune system: The body's defense method, characterized by a high degree of resistance to specific foreign substances.

Infiltration: The accumulation in a tissue of substances not normal to it or in amounts in excess of the normal.

Infusion: In **this report, the slow,** prolonged **injection of a** fluid into the body.

Infusion pump: **A** device that moves an infused fluid into the body under positive pressure.

Inpatient **services: Care** that includes an overnight stay in a medical facility.

Intravenous drug administration: Entrance **of a drug into the body by way of a vein.**

Length **of stay (LOS): The** number **of days a** patient remains in **the** hospital from admission to discharge.

Licensed practical nurse: **A nurse** with usually 12 months of practical **nursing training and** licensure, as opposed to a registered nurse with a four year baccalaureate degree and licensure.

Marginal **cost: The** incremental cost to the provider or supplier **of serving one** more patient.

Medicaid: **A** Federal-State **medical assistance** program authorized in 1965 to pay for **health care services** used by people who meet income and other requirements. Eligibility requirements and benefits vary **from** State **to** State.

Medicare: **A** nationwide, federally administered health insurance program authorized in 1965 **to cover the cost** of services for eligible persons over age 65, persons receiving Social Security Disability Insurance **payments** for 2 years, and persons with end-stage renal disease. **Medicare** consists of two separate but coordinated programs-hospital insurance **(Part A) and** supplementary medical insurance (Part B). Health insurance protection **is** available **to insured** person without regard **to income.**

Medicare beneficiary: One who receives coverage for health services under **Medicare.**

Medicare intermediaries **or** carriers: Fiscal agents **(typically Blue Cross** plans **or** commercial insurance **firms)** under contract to the Health Care **Financing** Administration for administration **of specific Medicare tasks. These tasks** include determining reasonable costs for covered items and services, making payments, and guarding against unnecessary use of covered services. In this report, intermediaries and carriers are collectively referred to as fiscal intermedi***aries.***

Metabolism: The totality of chemical processes occurring in **a living** organism.

Narcotic: **A drug that** dulls the senses, relieves pain, and induces profound sleep.

Neoplastic disease: **A** condition causing or resulting in tumor formation.

Nosocomial infection: An infection originating in **a** hospital.

Osteomyelitis: Infection of the bone.

Outpatient facility: **A healthcare facility** where medical services are provided to patients who are not inpatients **of** hospitals.

Palliative treatment: Treatment whose goal is patient comfort rather than cure.

Parenteral drug administration: Entrance **of a drug into the body by means** other than through the digestive tract.

Peer **Review** Organization: Organizations established in 1982 (Public Law 97-248) **with** which **the U.S.** Department of Health and Human Services contracts **to** review the appropriateness **of settings of care and the** quality **of care** provided to Medicare beneficiaries.

Per capita payment: **A** payment rendered **to a** provider, typically **on a** monthly basis, **to cover costs** of all care provided **to that** patient during a given time period.

Primary **care** physician: **A** physician who provides basic first-line **medical care,** such **as a** practitioner, general pediatrician, obstetrician/gynecologist, and general internist.

Prospective payment: Payment for **medical care on the basis of rates set in advance of the time period in**which they apply. The unit of payment may vary from individual medical services to broader **categories,** such **as** hospital case, episode of illness, or person (cavitation).

Prosthetic **device: An artificial** replacement for **a missing (or** nonfunctional) body part.

Pulmonary embolism: The sudden obstruction of a blood vessel in the lungs by an abnormal particle circulating in the blood.

Quality assessment: Measurement and evaluation of the quality of health care provided to individuals or to groups of patients.

Quality assurance: Conduct of activities that safeguard or improve the quality of health care by correcting deficiencies found through quality assessment.

Retrospective payment: A payment method for health care services in which hospitals (or other providers) are paid for services rendered after the service has taken place. In this country, the term has traditionally referred to hospital payment, since other providers have generally been paid on the basis of charges instead of costs.

Secondary infection: A second infection occurring in a person already suffering from an infection of another nature. For example, a person being treated by drug infusion for a bone infection could become secondarily infected as a result of organisms entering the body through a catheter.

Septicemia: The presence of disease-causing bacteria in the bloodstream.

Skilled nursing facility: **A** subacute or **long-term care facility that provides skilled nursing care (i.e., care that requires the expertise of a trained nurse).**

Subcutaneous drug administration: Entrance of a drug into the body by means of a needle or catheter inserted under the skin.

Swing-bed: Licensed acute-care beds designated by a hospital to provide either acute or long-term care services. A hospital qualifying to receive Medicare and Medicaid reimbursement for care provided to swing-bed patients must be located in a rural area (as defined by the U.S. Bureau of the Census), have less than 100 acute-care beds, and (when applicable) must have received a certificate of need for the provision of long-term care services from its State health planning and development agency.

Third-party payer: Payment by a private insurer or government program to a medical provider for care given to a patient.

Thrombocytopenia: A condition that results in a fewer than normal number of platelets per unit volume of blood.

Thromboembolic disease: Obstruction of a blood vessel with thrombotic material carried by the bloodstream from the site of origin to plug another vessel.

Thrombophlebitis: Inflammation of a vein associated with thrombus formation.

Thrombus: An aggregation of blood factors, primarily platelets; a clot. If the clot detaches and moves elsewhere in the bloodstream, it is termed an embolus.

Total parenteral nutrition: A feeding system that includes all the nutrients needed by the body and that is introduced into the body intravenously.

Vascular system: The body's network of arteries, veins, and capillaries.

Vein: A vessel that carries blood from various organs or parts back to the heart.

Vesicant: A substance capable **of inducing discharge or blister.**

REFERENCES

REFERENCES

1. Abbott, D. A., President, Association for Practitioners in Infection Control, Mundelein, IL, comments on, "Proposed Conditions of Participation for Home IV Drug Therapy Providers," issued pursuant to the Medicare Catastrophic Coverage Act of 1988, submitted to the Health Care Financing Administration on September 18, 1989.
2. Abbott Laboratones, Inc., informational literature for Abbokinase® Open-Cath, urokinase for catheter clearance (North Chigaco, IL: Abbott Laboratories, 1986).
3. ABEL Health Management Services, Inc., Great Neck, NY, informational visit with OTA staff and informational materials, Nov. 9, 1990.
4. Adams, P.F., and Hardy, A.M., "Current Estimates of the National Health Interview Survey: United States, 1988," ***Vital and Health Statistics, Series*** 10, No. 173, DHHS Pub. No. 89-1501, National Center for Health Statistics, Public Health Service, U.S. Department of Health and Human Services (Washington, DC: U.S. Government Printing Office, 1989).
5. Allcutt, D.A., Lort, D., and McCollum, C.N., ''Final In-line Filtration for Intravenous Infusions: A Prospective Hospital Study,' ***British Journal of Surgery*** 70(2):111-113, ***1983.***
6. **Alper, P.R., "Count Me out of the Home-Care Boom,"** ***Medical Economics*** 62(8):90-93, April 1985.
7. American Association of Blood Banks, ***Home Transfusion Therapy,*** Snyder, E.L. and Menitove, J.E. (eds.) (Arlington, VA: American Association of Blood Banks, 1986).
8. American Association of Blood Banks, ***Improving Transfusion Practice: The Role of Quality Assurance,*** Kurtz, S., Summers, S., and Kruskall, M. (eds.) (Arlington, VA: American Association of Blood Banks, 1989).
9. American College of Surgeons statement, presented by Edward Seljeskog, and statement of the American College of Radiology, presented by Lee Rogers, hearings on H.R. 939, June 1989.
10. American Hospital Association, ***Hospital Statistics, 89-90 ed.*** (Chicago, IL: American **Hospital Association, 1989).**
11. **American Medical Association,** ***American Medical Association Drug Evaluations, 6th Ed. (Chi***cago, IL: American Medical Association, 1986).
12. American Medical Association, Council on Scientific Affairs, "Educating Physicians in Home Health Care," ***Journal of the American Medical Association*** 265(6):769-771, **February 13, 1990.**
13. American Medical Association statement, presented by James Todd, hearing on H.R. 939, March 1989.
14. American Society of Hospital Pharmacists, Bethesda, MD, informational visit with OTA staff, August 28, 1990.

14a. Amgen Inc., Thousand Oaks, CA, ***Neupogen (Filgrastim)*** product literature, February 21,1991.

15. Anne Arundel General Hospital, Outpatient Home IV Therapy Services Program, Annapolis, MD, informational site visit by OTA staff, October 25, 1990.
16. Antoniskis, A., Anderson, B.C., Volkinburg, J.V., et al., "Feasibility of Outpatient Self-administration of Parenteral Antibiotics," ***The Western Journal of Medicine*** 128(3):203-206, ***1978.***
17. Ashida, E.R., and Saxon, A., "Home Intravenous IrnmunoglobulinTherapyby Self-administration,' ***Journal of Clinical Immunology*** 6(4):306-9, ***1986.***
18. **Ashton, J., Gibson, V., and Summers, S., "Effects of Heparin Versus Saline Solution on Intermittent Infusion Device Irrigation,'** ***Heart Lung 19(6):608-612,*** November 1990.
19. Baker, C., and Kramer, N., "Employer-Sponsored Prescription Drug Benefits," ***Monthly Labor Review*** **114(2):31-35,** 1991.
20. Baker, J., Office of program Development, Office of CHAMPUS, Office of Deputy Assistant Secretary of Defense for Health Services Financing, Office of the Assistant Secretary of Defense for Health Affairs, DOD, Aurora, CO, personal communication, March 18, 1991.
21. Balinsky, W., "Reimbursement for Outpatient Parenteral Antibiotic Therapy: Update," ***Reviews of Infectious Diseases*** 13(Suppl. *2):* S193-195, ***1991.***
22. Balinsky, W., and Nesbitt, S., "Cost-Effectiveness of Outpatient Parenteral Antibiotics: A Review of the Literature," ***American Journal of Medicine*** 87(3):301-305, September 1989.
23. Baptista, R.J., and Mitrano, F. P., "Experience With 211 Courses of Home Intravenous Antimicrobial Therapy,'' ***American Journal of Hospital Pharmacy*** 46:315-316, ***1989.***
24. Barfoot, K.R., and Ross, K.L., "I.nt.ravenous Therapy at Home: An Overview," ***Home Healthcare Nurse*** 6(4):11-13, ***1988.***
25. **Barget,** C.D., and Zink, M.R., "Evaluation of Clinical Indicators in IV Home Care," ***Journal of Nursing Quality Assurance*** 3(3):64-74, May ***1989.***
26. Bates, I. J., Vice President, National Hospice Organization, Arlington, VA, personal communica-

297-913 0 - 92 - 14

tion, October 2, 1990.
27. Baumgartner, T.G., Schmidt, G.L., Thakker, K.M., et al., "Bacterial Endotoxin Retention by In-line Intravenous Filters," *American Journal of Hospital Pharmacy* 43(3):681-684, March 1986.
28. Baxter Healthcare Corp., "Infuser Product Overview," Washington, DC, 1989.
29. Baxter Healthcare Corp., ''Intermater Elastomeric Infusion Device," Washington, DC, 1990.
30. Beresford, L., "Growing Pains for Hospices," *Business and Health* 8(9):52-62, September 1990.
31. Berkman, S.A., Lee, M.L., and Gale, R.P., "Clinical Uses of Intravenous Immunoglubulins,'' *Annals of Internal Medicine* 112(4):278-92, *1990.*
32. Berkow, R. (cd.), *The Merck Manual,* 15th ed. (Rahway, NJ: Merck& Co., 1987).
33. Biere, D., Home Care Accreditation Program, Joint Commission on the Accreditation of Healthcare Organizations, Oakbrook Terrace, IL, personal communications, Sep. 14, 1990, Oct. 14, 1991, and Feb. 20, 1992.
34. Biomedical Business International, 1989, as cited in *Home Health Line,* "Tax-Exempt VNAS and Hospitals Must Tell IRS More About Their Income From For-Profit Activities," vol. xv, pp. 93-95, March 7,1990.
35. Bishop, C.T., "Home Parenteral Chemotherapy," *Topics in Hospital Management* 4(3):35-42,1984.
36. Black, B., American Society of Hospital Pharmacists, Bethesda, MD, personal communication, January 18, 1991.
37. Blackledge, F., Jefferson County Department of Health, Birmingham, AL, personal communication, November 1, 1990.
38. Blair, D., Department of Infectious Diseases, School of Medicine, State University of New York at Syracuse, Syracuse, NY, personal communication, Oct. 15, 1990.
39. Blazer, D., and Williams, C. D., "Epidemiology of Dysphoria and Depression in an Elderly Population,'' *American Journal of Psychiatry 137(4):439-443,* April *1980.*
40. Block Medical, Inc., Carlsbad, CA, marketing literature for Homepump™ Disposable Elastomeric Infusion System and Verifuse™ Ambulatory Infusion Pump, November 1990.
41. Blue Cross and Blue Shield of Michigan, unpublished study, 1984, as cited in U.S. Congress, Library of Congress, Congressional Research Service, "Medicare: Physician Referrals to Clinical Laboratories," prepared by Jennifer O'Sullivan, Washington, DC, September 1990.
42. Blue Cross and Blue Shield of the National Capital Area, Washington, DC, "Guidelines for Participation for Home Care Providers," February 1989.
43. Bodenheimer, L., and Thomsen, K., Blue Cross/Blue Shield of the National Capitol Area, Washington, DC, personal communication, July 28, 1991.
44. Booth, P., Director, Division of Review Programs, Health Standards and Quality Bureau, Health Care Financing Administration, U.S. Department of Health and Human Services, Baltimore, MD, personal communications, September 1990 and October 1991.
45. Bradley, L., Bureau of Program Operations, Health Care Financing Administration, Baltimore, MD, personal communication, October 16, 1990.
46. Brook, H., Deputy Director, Office of Peer Review, Health Standards and Quality Bureau, Health Care Financing Administration, Baltimore, MD, personal communication, February 26,1992.
47. Brook, R.H., and Appel, F.A., "Quality-of-Care Assessment: Choosing a Method for Peer Review,'' *New England Journal of Medicine 288(25):1323-1329,* June 21, 1973.
48. Brook, R.H. and Lohr, K.N., "Efficacy, Effectiveness, Variations, and Quality," *Medical Care* 23(5):710-722, *1985.*
49. Brown, J. M., "Innovative Antibiotic Therapy at *Home,* ''*Journal of Intravenous Nursing 11(6):397-401,* November/December 1988.
50. Brown, J.M., "Peripherally Inserted Central Catheters—Use in Home Care," *Journal of Intravenous Nursing* 12(3):144-150, May/June 1989.
51. Brown, R. B., "Prescribing Antibiotics in Home Health Care: Problems and Prospects," *Geriatrics* 43(12):43-49, December 1988.
52. Bruton, O. C., "Agarnmaglobulinemias,' *Pediatrics* 9:722-727, *1952.*
53. Buchanan, R., Director of Medical Review, American Medical Peer Review Association, Washington, DC, personal communication, November 30, 1990.
54. Buckley, R.H., and Wood, A.J.J., "The Use of Intravenous Immune Globulin in Immunodeficiency Diseases,' New *England Journal of Medicine* 325(2):110-117, *1991.*
55. Buco, M., Blue Cross and Blue Shield Association, Chicago, IL, personal communication, November 29, 1990.
56. Burney, I., Hickman, P., and Paradise, J., et al., "Medicare Physician Payment, Participation, and Reform," *Health Affairs* 3(4):5-24, *1984.*
57. Burney, I., and Schieber, G., "Medicare Physician Services: The Composition of Spending and Assignment Rates," *Health Care Financing Review* 7(1):81-96, *1985.*
58. Califano, J. A., Jr., *America's Health Care Revolution: Who Lives? Who Dies? Who Pays? (New* York, NY: Random House, 1986).

59. Capitman, J.A., "Case Management for Long-Term and Acute Medical Care," ***Health Care Financing Review*** **annual** supplement, pp. 53-55, 1988.

60. Cardinale, V.A. (cd.), ***Red Book Drug Topics*** (Oradell, NJ: Medical Economics Data, 1991).

61. Carlson, C., "National Phlebitis Rates," ***Journal of the National Infusion Therapy Association: Update*** 6(6):5, ***1985.***

62. Carlson, K.R., and Mechanic, J., "IV Therapy in Long-Term Care: Bridging the Gap," ***Journal Intravenous Nursing*** 11(4):236-238, July/August 1988.

63. Catania, P., and Castillo, G., 'State Boards Setting New Standards for Home Care," ***U.S. Pharmacology*** 3:86-92, March 1988.

64. Catchpole, A., "CysticFibrosis: Intravenous Treatment at Home,' ***Nursing Times*** 85(12):40-2, ***1989.***

65. Chattopadhyay, T., Catania, P.N., Mergener, M.A., ''Therapeutic Outcome of Elderly and Nonelderly Patients Receiving Home Intravenous Antimicrobial Therapy," ***American Journal of Hospital Pharmacy*** 47(2):335-9, 1990.

66. Chawla, A. J., and Thran, S., Physician Ownership of Health Care Facilities, ***Socioeconomic Characteristics of Medical Practice*** (Chicago, IL: American Medical Association, AMA Center for Health Policy Research, 1989), p. 9-15.

67. Christianson, J., "Provider Participation in Competitive Bidding for Indigent Patients in Arizona," ***Inquiry*** 21(2):161-177, ***1984.***

68. Christianson, J., and Hillman, D., "Competitive Bidding as a Cost Containment Strategy for Indigent Medical Care: The Implementation Experience in Arizona," ***Journal of Health Politics, Policy, and Law*** 9(3):427-452, ***1984.***

69. Christianson, J., Hillman, D. G., and Smith, K., "A Comparison of Existing and Alternative Competitive Bidding Systems for Indigent Medical Care," ***Social Science and Medicine*** 18(7):599-604, ***1984.***

70. Christianson, J., Kirkman-Liff, B., and Hillman, D., "An Analysis of Competitive Bidding by Providers for Indigent Medical Care Contracts," ***Health Services Research*** 20(5):549-577, ***1985.***

71. Christianson, J., and Smith, K.R., "Options in the Design of Competitive Bidding Processes for Indigent Medical Care," ***Contemporary Policy Issues*** (Supplement ***to Economic Inquiry), 3(2):55-68, 1984.***

72. Cole, M. G., "Flushing Heparin Locks: Is Saline Flushing Really Cost-Effective?" *Journal Intravenous Nursing* 12(Suppl. *1):* S23-S29, *1989.*

73. Collins, J.A., Skidmore, M.A., Melvin, D. B., et al., "Home Intravenous Dobutamine Therapy in Patients Awaiting Heart Transplantation," *Journal of Heart Transplant 9(3* part 1):205-208, 1990.

74. Commerce Clearing House, Inc., ***Medicare and Medicaid Guide*** (Chicago, IL: Commerce Clearing House, Inc., 1990).

75. Conrad, J., Chief, Part B Communications Branch, Division of Carrier Procedures, Bureau of Program Operations, Health Care Financing Administration, Baltimore, MD, personal communication, Oct. 15, 1990.

76. Cooper, M., Health Care Financing Administration, Baltimore, MD, personal communication, October 16, 1990.

77. Cooperative Group for the Study of Immunoglobulin in Chronic Lymphocytic Leukemia, "Intravenous Immunoglobulin for the Prevention of Infection in Chronic Lymphocytic Leukemia,'' New ***England Journal of Medicine*** 319(14): ***902-907,*** Oct. 1988.

78. Corby, D., Schad, R.F., and Fudge, J.P., "Intravenous Antibiotic Therapy: Hospital to Home," ***Nursing Management*** 17(8):52-61, ***1986.***

79. Corona, M.L., Peters, S.G., Narr, B.J., et al., "Infections Related to Central Venous Catheters," Mayo ***Clinic Proceedings*** 65(7):979-986, ***1990.***

80. Cosentino, F., "Central Venous Catheters," ***Principles and Practice of Intravenous Therapy 4th*** Edition, Plumer, A.L. and Cosentino, F. (eds.) (New York, NY: Little, Brown and Co., 1987).

81. Cosentino, F., "Risk Management and Quality Assurance," ***Principles and Practice of Intravenous Therapy 4th Edition,*** A.L. Plumer and F. Cosentino (eds.) (New York, NY: Little, Brown and Co., 1987).

82. Coulam, R.F., "Abt Associates Evaluation of Medicare Reimbursement for Durable Medical Equipment," paper presented at conference sponsored by the Health Industry Distributors Association, Washington, DC, April 15, 1991.

83. Crawford, R.B., Vital Care, Inc., Livingston, AL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, December 17, 1990.

84. Crocker, K. S., Devereaux, G.B., Ashmore, D.L., et al., "Clinical Evaluation of Elastomeric Hydrogel Peripheral Catheters During Home Infusion Therapy," ***Journal of Intravenous Nursing 13(2):89-97,*** April 1990.

85. Culbertson, V.L., Rhodes, R. S., Hill, E.P., and Jrohes, P.J., "Impact of Home Infusion Therapy on the Colorado Medicaid Program Budget," *American Journal of Hospital Pharmacy 45(6): 1346-1349, 1988.*

86. ***Curtin,*** M., Quality Assurance Manager, Omni-Flow Laboratories, Wobum, MA, personal com-

munication, Feb. 8, 1991.

87. Dans, P.E., Weiner, J.P., and Otter, S.E., "Peer Review Organizations: promises and Pitfalls," New *England Journal of Medicine* 313(18):1 *131-1137,* October 1985.
88. David, T.J., "Intravenous Antibiotics at Home in Children With Cystic Fibrosis," *Journal of the Rural Society of Medicine* 82(3):130-1, *1989.*
89. Davis, K., "Economic Theories of Behavior in Nonprofit Private Hospitals," *Economic and Business Bulletin* 24(2):1-13, *1972.*
90. Davis, T. C., et al., "The Gap Between Patient Reading Comprehension and the Readability of Patient Education Materials," *Journal of Family Practice* 31(5):533-538, *1990.*
91. Debure, A., Chkoff, N., Chatenoud, L., et al., "One-Month Prophylactic Use of OKT-3 in Cadaver Kidney Transplant Recipients," *Transplantation* 45(3):546-553, *1988.*
92. Dehn, T.G., President of the American Medical Peer Review Association, testimony at hearing on the Medicare Quality Assurance Process before the Subcommittee on Intergovernmental Relations and Human Resources, Committee on Government Operations, House of Representatives, U.S. Congress, Washington, DC, October 20, 1987.
93. Delaney, C. W., and Lauer, M.L., *Intravenous Therapy: A Guide to Quality Care* (Philadelphia, PA: J.B. Lippincott Co., 1988).
94. Dies, F., Krell, M.J., Whithlow, P., et al., "Intermittent Dobutamine in Ambulatory Outpatients With Chronic Cardiac Failure," *Circulation* 74(Suppl.):38, 1986.
95. Dixon, J., Community Health Accreditation Program, National League for Nursing, New York, NY, personal communications, Mar. 21, 1991, Nov. 7, 1991, and Feb. 27, 1992.
96. Dolbee, S.F., and Creason, N. S., "Outcome Criteria for the Patient Using Intravenous Antibiotic Therapy at Home," *Home Healthcare Nurse* 6(4):22-29, **July-August 1988.**
97. **Dombi, W. A., Director, Center for Health Care Law, Washington, DC, personal communication, Oct. 5, 1990.**
98. **Donabedian, A., "Evaluating the Quality of Medical Care,"** *Milbank Memorial Fund Quarterly 44(3),* Part 11:166-206, fall 1966.
99. Donlan, T. A., "Medicare Goes Home," *Barron's, pp. 17,20,* July 1989.
100. DuPen, S. L., Seattle, WA, "Epidural Morphine: Preservatives or Not?" Swedish Hospital Medical Center, April 1987.
101. Eisenberg, J. M., and Kitz, D. S., "Savings From Outpatient Antibiotic Therapy for Osteomyelitis: An Economic Analysis of a Therapeutic Strategy,'' *Journal of the American Medical Association* 255(12):1584-1588, *1986.*
102. **Ellis, J.M., "Let Parents Give the Care: IV Therapy at Home in Cystic Fibrosis,"** *The Professional Nurse* 4(12):587-592, 1989.
103. Emergency Care Research Institute, "Evaluation: General Purpose Infusion Pumps," *Health Devices* 18(3-4):92-133, March-April 1989 (ECRI).
104. Epperson, E. L., "Efficacy of 0.9% Sodium Chloride Injection With and Without Heparin for Maintaining Indwelling Intermittent Injection Sites," *Clinical Pharmacology* 3(6):626-629, November/December 1984.
105. Ernst & Whinney, *The Impact of PROS on Hospitals* 13&W No. J58693 (Cleveland, OH: Ernst and Whinney, 1987).
106. Eron, L.J., "Intravenous Antibiotic Administration in Outpatient Settings," *Infectious Diseases* 14(1):4-11, *1984.*
107. Falchuk, K.H., Peterson, L., and McNeil, B.J., ''Microparticulate-induced Phlebitis: Its Prevention by In-line Filtration," New *England Journal of Medicine* 312(2):78-82, 1985.
108. **Farmer, H. F., "Home Health Care: Another Emerging Mr. Hyde?" [letter],** *Journal of the Florida Medical Association* 77(9):794, September 1990.
109. Faxon, C., Parenteral and Alimentation Providers Alliance, Monterey, CA, personal communication, Dec. 12, 1990.
110. Feder, J., Hadley, J., and Zuckerman, S., "How Did Medicare's Prospective Payment System Affect Hospitals?" New *England Journal of Medicine,* 317(14):867-873, Oct. 1, 1987.
111. Feldstein, P. J., *Health Care Economics (New* York, NY: John Wiley & Sons, 1988).
112, Feldstein, P.J., *The Politics of Health Legislation (Ann* Arbor, MI: **Health Administration Press, 1988).**
113. **Ferris, A.K.,** and Wyszewianski, L., "Quality of Ambulatory Care for the Elderly: Formulating Evaluation Criteria," *Health Care Financing Review* 12(1):31-38, fall 1990.
114. Ford, M., "Medicaid: FY 1991 Budget and Child Health Initiatives," CRS Issue Brief *90043,* U.S. Congress, Congressional Research Service, Washington, DC, February 12, 1990.
115, Forry, L.M., Universal Management Systems, Inc., Newton Square, PA, personal communication, October 22, 1990.
116. Fraschini, G., Yap, H., Hortobagyi, G.N., et al., ''Five-day Continuous-Infusion Vinblastine in the Treatment of Breast Cancer," *Cancer* 56:225-9, *1985.*
117. Friedland, G., "Infusion-related Phlebitis—Is the In-line Filter the Solution?" New *EnglandJournal of Medicine* 312(2):113-114, *1985.*

118. Fries, B.E., and Mooney, L.M., ''Resource Utilization Groups: A Patient Classification System for Long-Term Care," *Medical Care* 23(2):110-112, *1985.*

119. Gainer, R.B., and Smego, R.A., "Intravenous Home Antibiotic Therapy,' The Supplement, vol. 1 (Educational Service to the Professions by HNS)(Pine Brook, NJ: Health Dyne Co., 3-12, 1985).

120. Gait, M.A., and Gait, K.A., "Pharmaceutical Services in Hospital-Based Home Care Agencies—1982," *American Journal of Hospital Pharmacy* 41:2355-2359, November 1984.

121. Gardner, C., "Home IV Therapy: Part I," *Journal of the National Infusion Therapy Association* 9:95-103, *March/April 1986.*

122. Gardulf, A., Harnmarstom, L., Smith, C. I.E., "Home Treatment of Hypogammaglobulinaemia With Subcutaneous Gammaglobulin by Rapid Infusion," *Lancet* 338:162-166, 1991.

123. Garratty, G., "Severe Immune Haemolytic Anaemia Associated With Newer Cephalosporins" [letter], *Lancet* 338:119-120, 1991.

124. Garrelts, J. C., LaRocca, J., Ast, D., et al., "Comparison of Heparin and 0.9% Sodium Chloride Injection in the Maintenance of Indwelling Intermittent IV Devices,' *Clinical Pharmacology 8:34-39,* January 1989.

125. Gentry, L. O., "oral Antimicrobial Therapy for Osteomyelitis" [letter], *Annals of Internal Medicine* 114(11):986-987, *1991.*

126. Gentry, L. O., and Rodriguez-Gomez, G., "Oral Ciprofloxacin Compared with Parenteral Antibiotics in the Treatment of Osteomyelitis,' *Antimicrobial Agents and Chemotherapy* 34:40-43, *1990.*

127. Gibson, I., Director, Division of Program Operations, Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration, Baltimore, MD, personal communication, Jan. 11, 1991.

128. Gilbert, J., Robinson, T., and Littlewood, J.M., ''Home Intravenous Antibiotic Treatment in Cystic Fibrosis," *Archives of Disease in Children* 63:512-7, *1988.*

129. Gilman, A.G., Goodman, L. S., Rail, R.W., and Murad, F., *Goodman and Gilman's The Pharmacological Basis of Therapeutics (New* York, NY: MacMillan Publishing Co., 1985).

130. Ginsburg, P., and LeRoy, L.B., Hammons, G.T., "Medicare Physician Payment Reform," *Health Affairs* 9(1):178-188, *1990.*

131. Goldenberg, R. I., "Pitfalls in the Delivery of Outpatient Intravenous Therapy," *Drug Intelligence and Clinical Pharmacy* 19:293-296, April 1985.

132. Goldman, M., Division of Hospitals and Ambulatory Services, Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration, Baltimore, MD, personal communication, March 19, 1991.

133. Gong, J., Director of Reimbursement, American Health Care Association, Washington, DC, personal communications, November 1991.

134. Gorski, L.A., "Effective Teaching of Home IV Therapy," *Home Healthcare Nurse* 5(5):10-17, September-October 1987.

135. Graves, G., Jackson, J.P., Maxwell, A., et al., ''Home Intravenous Antibiotic Therapy in Arkansas," *Journal of Arkansas Medical Society 84(1):55-57, 1987.*

136. Graves, G., Maxwell, A., and Woods, T., "Home Intravenous Antibiotic Therapy in Arkansas: A Study," *National Association of Retail Druggist Journal* 108(9):22-24, *1986.*

137. Gray, B.H. (ed.), *Committee on Implications of For-profit Enterprise in Health Care (Washing*ton, DC: National Academy Press, 1986).

138. Groshong[tm] catheter product literature, Dazol, Inc., Cranston, RI, 1989.

139. Gurland, B.J., "The Comparative Frequency of Depression in Various Adult Age Groups," *Journal of Gerontology* 31(3):283-292, May 1976.

140. Hadaway, L. C., "An Overview of Vascular Access Devices Inserted via the Antecubital Area," *Journal of Intravenous Nursing* 13(5):297-306, September/October 1990.

141. Hadaway, L. C., Clinical Nursing Educator, Eastern Region, Menlo Care, Inc., Menlo Park, CA, personal communication, February 4, 1991.

142. Hadaway, L. C., Clinical Nurse Educator, Menlo Care, Inc., Menlo Park, CA, personal communication, September 3, 1991.

143. Hadley, J., "Physician Participation in Medicaid: Evidence From California," *Health Services Research* 14:266-280, *1979.*

144. Hamilton, R.A., Plis, J.M., Clay, C., et al., ''Heparin Sodium Versus 0.9% Sodium Chloride Injection for Maintaining Patency of Indwelling Intermittent Infusion Devices," *Clinical Pharmacy* 7:439-443, June 1988.

144a. Handmaker Home Health Services, Inc., site visit by OTA staff, May 2, 1991.

145. Handy, C.M., "Vascular Access Devices. Hospital to Home Care," *Journal of Intravenous Nursing* 12 (Suppl. 1): S10-S18, January/February 1989.

146. Harding, S., I.V. Program Director, Infections Limited, Tacoma, WA, personal communication, July 1991.

147. Harrigan, C.A., "Care and Cost-Justification of Final Filtration,' *Journal of the National Infusion*

Therapy Association 8(5):426-430, September/October 1985.

148. Harris, L.F., Buckle, T.F., and Coffey, F.L., "Intravenous Antibiotics at Home," ***Southern Medical Journal*** 79(2):193-196,1986.

149. Health Industry Distributors Association, site visit by OTA staff to New England Critical Care and Caremark facilities in Columbia, MD, August 2, 1990.

150. Health Insurance Association of America, ***Source Book of Health Insurance Data*** (Washington, DC: Health Insurance Association of America, 1991).

151. Health News Daily, "GM-CSF Approved March 5 for Use With Autologous Bone Marrow Transplants," ***Health News Daily,*** pp. 5-6, 1991.

152. Held, P., Holahan, J., and Carlson, C., "The Effect of Medicaid and Private Fees on Physician Participation in California's Medicaid Program, 1974-78," Working Paper No.1306-02-01, The Urban Institute, Washington, DC, 1983.

153. Henricks, M., "Home Health Care Gets a Shot in the Arm," ***Venture,*** September 1989, pp. 42-46.

154. Hickey, R.F., Cason, B.A., and Charles, R., "Lower Incidence of Intravenous Catheter Complications With an Elastomeric Hydrogel Catheter," ***Anesthesia and Analgesics*** 68(2S):121, ***1989.***

155. Higbee, D., Chief, Catastrophic and Medical Services Branch, Division of Medical Services Coverage Policy, Office of Coverage Policy, Bureau of Policy Development, Health Care Financing Administration, Baltimore, MD, personal communication, October 16, 1990.

156. Higbee, D., Chief, Catastrophic and Medical Services Branch, Division of Medical Services Coverage Policy, Office of Coverage Policy, Bureau of Policy Development, Health Care Financing Administration, Baltimore, MD, personal communication, November 5, 1990.

157. Hillman, B.J., Joseph, C.A., Mabry, M.R., et al., "Frequency and Costs of Diagnostic Imaging in Office Practice—A Comparison of SeU-Referring and Radiologist-Referring Physicians," ***The New England Journal of Medicine*** 323(23):1604-1608, December 6, 1990,

158. Hindman, M. J., Vital Care, Inc., Livingston, AL, personal communication, Nov. 3, 1990.

159. Hogan, A., "Competitive Bidding and Voucher Payments for Implementing the New Federalism With Special Emphasis on Programs for the Aging," *Socio-Economic Planning Sciences, 17(1):33-37, 1983.*

160. Home Health Line, "VNAs Go Competitive With New Marketing Group," vol. VIII, p. 81, May 6, 1983.

161. Home Health Line, "The Competition . . .," vol. XV, p. 443, December 5, 1990.

162. Home Health Line, "The Competition. . .," vol. XVI, p. 91, March 13, 1991.

163. Home Health Line, "NYC VNS' Carol Raphael Talks About Home Care and the Urban Poor,' vol. XVI, pp. 110-113, March 27, 1991.

164. Home Health Line, "The Competition. . .," vol. XVI, p. 250, July 10, 1991.

165. Hommes, D.W., Bura, A., Mazzolai, L., et al., "Subcutaneous Heparin Compared with Continuous Intravenous Heparin Administration in the Initial Treatment of Deep Vein Thrombosis," ***Annals of Internal Medicine*** 116(4):279-284, February 1992.

166. Hook, M.L., and Ose, P., "Heparin vs. Normal Saline" [letter], ***Journal of Intravenous Nursing*** 13(3):150-151, ***1990.***

167. Hoyer, T., Director, Division of Provider Services Coverage Policy, Office of Coverage Policy, Bureau of Policy Development, Health Care Financing Administration, Baltimore, MD, personal communication, September 27, 1990.

168. HMSS, Inc., Phoenix, AZ, site visit by OTA staff, May 3, 1991.

169. Hsiao, W. C., "Estimating Physicians' Work for a Resource-Based Relative Value Scale," New ***England Journal of Medicine, 319(13)*** :889,1988b.

170. Hsiao, W. C., et al., "Results and Policy Implications of the Resource-Based Relative Value Scale,' New ***England Journal of Medicine 319(13);881-888,*** 1988a.

171. Hughes, C. B., "Giving Cancer Drugs IV; Some Guidelines," ***American Journal of Nursing 86:34-8, 1986.***

172. Infusaid™, Inc., Norwood, MA, totally implantable infusion pump product literature, 1989.

173. Institute of Medicine, ***Improving the Quality of Care in Nursing Homes*** (Washington, DC: National Academy Press, 1986).

174. Intravenous Nurses Society, "Intravenous Nursing Standards of Practice' (revised 1990), ***Journal of Intravenous Nursing*** Supplement 1990, April 1990.

175. Jacobs, P., "A Survey of Economic Models of Hospitals," ***Inquiry*** 11(2):83-97, ***1974.***

176. Jamopolis, S., Arlington, TX, personal communication, September 10, 1991.

177. Jefferson Home Infusion Service, Thomas Jefferson University Hospital, Philadelphia, PA, site visit by OTA staff, September 20, 1990.

178. Joint Commission on Accreditation of Healthcare Organizations, "Infection Control chapter from the 1991 ***Consolidated Standards Manual," Joint Commission Perspectives*** 10(3):E1-E5, May/June 1990 (newsletter of the Joint Commission on Accreditation of Healthcare Organizations).

179. Joint Commission on Accreditation of Healthcare Organizations, 1991 *Accreditation Manual for Home Care* (Oakbrook Terrace, IL: JCAHO, 1991).

180. Juba, D.A., "Medicare Physician Fee Schedules: Issues and Evidence From South Carolina," *Health Care Financing Review, 8(3); 57-67, 1987.*

181. Kaiser Permanence, Home Health Agency/ Hospice, Portland, OR, "Final Report of the Regional Infusion Therapy Task Force,' provided to OTA in December 1990.

182. Kalnins, I., "Home Health Agency Preferences for Staff Nurse Qualifications, and Practices in Hiring and Orientation,' *Public Health Nursing 6(2):55-61,* June 1989.

182a. Kane, R. E., Jennison, K., Wood, C., et al., "Cost Savings and Economic Considerations Using Home Intravenous Antibiotic Therapy for Cystic Fibrosis Patients," *Pediatric Pulmonology* 4:84-89, *1988.*

183. Kellie, S.E., and Kelly, J.T., "Medicare Peer Review Organization Preprocedure Review Criteria: An Analysis of Criteria for Three Procedures,' *Journal of the American Medical Association* 265(10):1265-1270, **March 13, 1991.**

184. **Kelton, J. G., Heddle, N.M., and Blajchman, M.A.,** *Blood Transfusion: A Conceptual Approach (New* York, NY: Churchill Livingstone, 1984).

185. Kerr, I. G., Sone, M., DeAngelis, C., et al., "Continuous Narcotic Infusion With Patient-Controlled Analgesia for Chronic Cancer Pain in Outpatients," *Annals of Internal Medicine* 108:554-557, *1988.*

186. Kimberly Quality Care, Inc., Atlanta, GA, informational visit with OTA staff, January 23, 1991.

187. Kind, A. C., Williams, D.N., and Gibson, J., "Outpatient Intravenous Antibiotic Therapy," *Post Graduate Medicine* 77(2):105-111, *1985.*

188. Kind, A. C., Williams, D. N., Persons, G., et al., "Intravenous Antibiotic Therapy at Home," *Archives of Internal Medicine* 139:413-415, *1979.*

189. Kleinfield, N.R., 'The Home Health Care Boom,' *The New York Times,* p. **D1, June 30, 1983.**

190. **Kobayashi, R.H., Kobayashi, A.D., Lee, N., et al., "Home Self-Administration of Intravenous Immunoglobulin Therapy in Children,"** *Pediatrics* 85(5):705-709, *1990.*

191. Kolek, G.B., "Continuous Ambulatory Gamma Globulin Infusion in the Home Setting: A Treatment Proposal for a High-risk Patient,' *Journal of Intravenous Nursing* 12(6):384-95, *1989.*

192. Komaroff, A.L., "Quality Assurance in 1984," *Medical Care* 23:723-734, *1985.*

193. Kozma, C. and Glaze, J., "Impact of Home IV Benefits on Beneficiary Utilization of Services," U.S. Department of Health and Human Services, Health Care Financing **Administration, Baltimore, MD, April 26, 1990.**

193a. **Kozma, C., School of Pharmacy, University of South Carolina, Columbia, SC, personal communication, September 10, 1991.**

194. **Lee, K., and Andrews, J.D., "Assessment of the Need for a Home Intravenous Antibiotic Program,"** *Canadian Journal of Hospital Pharmacy* 41(6):295-301, *307,* December 1988.

195. Lehman, M., Vital Choice Inc., Parenteral Alimentation Providers Association, Inc., Portland, OR, personal communication, January 1991.

196. Leier, C.V., Webel, J., Bush, C.A., "The Cardiovascular Effects of the Continuous Infusion of Dobutamine in Patients With Severe Cardiac Failure," *Circulation* 56:468-472, *1972.*

197. *Lerman,* D., "Survey: Non-Medicare Home Care a Financial Winner for Hospitals," *Hospitals* 65(1):30-31, January *5, 1991.*

198. *Lewis,* R.P., "Pharmacology of Modalities of Treatment,' *Canadian Journal of Cardiology* 6:10C-13C, 1990.

199. Liang, F.Z., Director, Government Affairs Division, American Society of Hospital Pharmacists, Bethesda, MD, letter to Louis W. Sullivan, Secretary, Department of Health and Human Services regarding Proposed Conditions of Participation for Home IV Drug Therapy Providers issued pursuant to the Medicare Catastrophic Coverage Act of 1988, Jan. 8, 1990.

200. Lohr, K.N., "Peer Review Organizations (PROS): Quality Assurance in Medicare," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1984.

201. Lokich, J., Bothe, A., Fine, N., et al., "The Delivery of Cancer Chemotherapy by Constant Venous Infusion," *Cancer* 50:2731-2735, *1982.*

202. Lonsway, R. A., "Care of the Patient With an Epidural Catheter: An Infection Control Challenge,' *Journal of Intravenous Nursing* 11(1):52-*55,* January/February 1988.

203. Lutz, S., "Home Care's Growth Hinges on Winning Over the Physicians," *Modern Healthcare,* September 29, 1989, pp. 20-30.

204. Lyons, J. M., Falkenbach, K., and Cerra, F.B., ' 'Home ParenteralNutrition With Full-Time Home Care Nurses," *Journal of Parenteral and Enteral Nutrition* 5(6):528-530, *1981.*

205. **Majerus, T. C., Dasta, J.F., Bauman, J.L., et al., ''Dobutamine: Ten Years Later,"** *Pharmacotherapy* 9(4):245-259, *1989.*

206. **Maki, D. G., Botticelli, J.T., LeRot,** M.L., et al., "Prospective Study of Replacing Administration Sets for Intravenous Therapy at 48- vs 72-Hour Intervals,' *Journal of the American Medical Association* 258(13):1777, October 1987.

207. Maki, D.G., Klein, B. S., McCormick, R.D., et al., ''Nosocomial *Pseudomonas pickettii* Bacteremias Traced to Narcotic Tampering," ***Journal of the American Medical Association*** 265(8):981-986, February 27, 1991.

208. Manning, W., ***Health Insurance and the Demand for Medical Care*** (Santa **Monica, CA: RAND Corp., 1988).**

209. **McAllister, J. C., "Home Health Care Services: Collaboration Alternatives, Vendor Selection and Program Implementation," *Topics in Hospital Pharmacy Management*** 4:56-71, November 1984.

210. McAllister, J. C., and Davis, S.M., "State Regulations for Home IV Therapy" [letter], ***American Journal of Hospital Pharmacy*** 46:1545-1546, August 1989.

211. McCall, N., et al., "Evaluation of Arizona Health Care Cost Containment System, 1984-85," ***Health Care Financing Review*** 9(2):79-90, ***1987.***

212. McCall, N., et al., "Evaluation of the Arizona Health Care Cost Containment System," Final Report, SRI International, January 1989.

213. McGuire, D.B., "Advances in Control of Cancer ***Pain,' 'NursingClinics of North America 22(3):677-90, 1987.***

214. McMillan, A., Lubitz, J., Newton, M., "Trends in Physician Assignment Rates for Medicare Services, 1968 -85,' ***Health Care Financing Review*** 7(2):59-75, ***1985.***

215. Medfusion, Inc., Duluth, GA, product literature for Walkmed[tm] and Infumed[tm] pumps, 1990.

216. Medical Economics Data, ***Physician's Desk Reference*** (Montvale, NJ: Medical Economics Co. Inc., 1992).

217. Medicine & Health, "HCFA Considering PRO Overhaul," ***Medicine & Health*** 45(2):1, Jan. **14, 1991.**

218. M-D-D-I Reports, ''Delmed Claims 10% of Home Dialysis Market; First Quarter Sales Climb 18.6%," May 23, 1983, p. 11.

219. Micheletti, J.A., and Shlala, T.J., "Evolving Quality Assurance Initiatives in Home Care," ***Nursing Management*** 20(8):24-28, August 1989.

220. Miller, P.C., "Home Blood Component Therapy: An Alternative," ***Journal of the National Infusion Therapy Association*** 9:213-217, May-June 1986.

221. Mitchell, J. B., and Cromwell, J., "Physician Behavior Under the Medicare Assignment Option," ***Journal of Health Economics*** 1(4):245-263, ***1982.***

222. Modem Healthcare, ''T[2] To Buy **Dallas-Based Home Infusion Company," *Modern Healthcare*** 20(45):18, ***1990.***

223. Monks, M., "Home Transfusion Therapy,' ***Journal of Intravenous Nurses*** 11(6):389-396, ***1988.***

224. Monk, M.R., Brown, T.R., Gamer, D.D., et al., "The Status of Home Intravenous Therapy Instruction Provided by U.S. Schools and Colleges of Pharmacy,' ***American Journal of Pharmaceutical Education*** 55:120-125, summer 1991.

225. Moraczewski, M., Reimbursement Analyst, Pharmacia Deltec, St. Paul, MN, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, October 7, 1991.

226. Moran, T.A., "AIDS: Current Implications and Impact on Nursing," ***Journal of Intravenous Nursing*** 12(4):220-226, July/August 1989.

227. Moulin, D.E., Kreeft, J.H., Murray-Parsons, N., et al., "Comparison of Continuous and Intravenous Hydromorphone Infusions for Management of Cancer Pain," ***Lancet*** 337:465-468, ***1991.***

228. Mulligan, S., Executive Vice President, Elan Corp., Ltd., Athlone, Ireland, personal communication, February 25, 1991.

229. Nadzam, D., Project Manager, Indicator Development, Department of Outcomes Research and Development, Joint Commission on the Accreditation of Healthcare Organizations, Oakbrook Terrace, IL, personal communication, April 15, 1991.

230. National Alliance for Infusion Therapy (formerly Alliance for Medical Nutrition), ***Standards for Home Infusion Therapy Providers*** (Washington, DC: NAIT, October 1990).

231. National Association of Boards of Pharmacy, ***Model Rules for Sterile Pharmaceuticals in NABP 84th Annual Meeting Proceedings*** (Chicago, IL: NABP, 1988).

232. National Association of Home Care, ***State Licensure and Certificate of Need Survey, March 1989*** (Washington, DC: NAHC, 1989).

233. National Association of Home Care, ***State Licensure and Certificate of Need Survey, March 1991*** (Washington, DC: NAHC, 1991).

234. National Institue of Child Health and Human Development Intravenous Immunoglobulin Study Group, "Intravenous Immune Globulin for the Prevention of Bacterial Infections in Children with Symptomatic Human Immunodeficiency Virus Infection," New ***England Journal of Medicine*** 325(2):73-80, ***1991.***

235. **National Institute of Health Consensus Conference, "Prevention and Treatment of Disease," *Journal of American Medical Association 264(24): 3189-3193, 1990.***

236. National Intravenous Therapy Association, ***NIXA Standards—IV Therapy Journal of the National Infusion Therapy Association*** 5(1):24-29, ***1982*** (as cited in Principles and Practice of IV Therapy).

237. National League for Nursing, Community Health Accreditation Program, ***Standards of Excellence***

for Home Care Organizations (New York, NY: National League for Nursing, 1989).

238. National Medical Care, Inc., Homecare Division, ***Central Line Catheter Care: Patient Information Guide*** (Waltham, MA: National Medical Care, Inc., 1989).

239. Nadzam, D., Project Manager, Indicator Development, Department of Outcomes Research and Development, Joint Commission on the Accreditation of Healthcare Organizations, Oakbrook Terrace, IL, personal communication, April 15, 1991.

240. Neiderpruem, M. S., "Factors Affecting Compliance in the Home IV Antibiotic Therapy Client,' ***Journal of Intravenous Nursing*** 12(3):136-142, May/June 1989.

241. Nelson, P.R., Vice President, Ambulatory Products, Ivion Corp., Broomfield, CO, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, October 7, 1991.

242. Short, P.A., Monheit, A., and Beauregard, K., "A Profile of Uninsured Americans," National Medical Expenditure Survey Research Findings 1, National Center for Health Services Research and Health Care Technology Assessment, Public Health Service, Department of Health and Human Services, DHHS Pub. No. (PHS) 89-3443 (Rockville, MD: 1989).

243. Nemur, D., Arizona Blue Cross/Blue Shield, Phoenix, AZ, personal communication, May 3, 1991.

244. Newhouse, J., "Toward a Theory of Nonprofit Institutions: An Economic Model of a Hospital," ***American Economic Review,*** 60(1):64-74, ***1971.***

245. Nicoll, L. H., "Heparin vs. Saline Debate' [letter], ***American Journal of Nursing*** 90(9):27, **September 1990.**

246. **Norwood, M., 'Home Care of the Terminally Ill,'** *American Journal of Hospital Pharmacy* 47(Suppl. 8):s23-s26, August 1990.

247. Ochs, H.D., Lee, M.L., Fisher, S.H., et al., "Self Infusion of Intravenous Immunoglobulin by Immunodeficient Patients at Home, ' ***Journal of Infectious Diseases 156(4)*** :652-654, ***1987.***

248. O'Donnell, K.P., "Physicians and Home IV Therapy: Roles and Risks," ***Caring*** 7(7):30-32, **July 1988.**

249. **O'Keiff, H., Barnes Home Health Services, Inc., St. Louis, MO, personal communications, January 4, 1991 and February 1991.**

250. **O'Keiff, H., Barnes Home Health Services, Inc., St Louis, MO, letter to the Office of Technology Assessment, U.S. Congress, Feb. 28, 1991.**

251. **Packer, M., Carver, J. R., Rodeheffer, R. J., et al., "Effect of Oral Milrinone on Mortality in Servere Chronic Heart Failure," New *England Journal of Medicine*** 325(21):1468-1475, November 1991.

252. Palmer, R.H., "The Challenges and Prospects for Quality Assessment in Ambulatory Care," ***Inquiry*** 25:119-131, *1988.*

253. Palmer, R. H., and Nesson, H.R., "A Review of Methods for Ambulatory Medical Care Evaluation," ***Medical Care*** 20:758-781, ***1982.***

254. Wringer, L., "Economic Incentives in the Provision of Long Term Care," in Jack Meyer (cd.), ***Mark-et Reforms in Health Care: Current Issues, New Directions, Strategic Decisions*** (Washington, DC: American Enterprise Institute, 1983).

255. Paringer, L., "Medicare Assignment Rates of Physicians: Their Responses to Changes in Reimbursement Policy," ***Health Care Financing Review 1(3), 1980.***

256. Parver, A., Executive Director, National Alliance for Infusion Therapy, Washington, DC, personal communication, September 1991.

257. Parver, A., and Lind, K., National Alliance for Infusion Therapy, Washington, DC, memorandum to the Office of Technology Assessment, U.S. Congress, Oct. 30, 1991.

258. Pauly, M.V., and Redisch, M., "The Not-for-Profit Hospital as a Physicians' Cooperative," ***American Economic Review*** 63(1):87-99, ***1973.***

258a. **Paxton, D., Cystic Fibrosis Foundation, Silver Spring, MD, personal communication, December 4, 1990.**

259. **Payer, L., *Medicine and Culture (New*** York, NY: Penguin, 1988).

260. Pelletier, G., CRNI, Nashua Memorial Hospital, Nashua, NH, personal communication, February 1, 1991.

261. Perivascular Nurse Consultants, Rockledge, PA, unpublished information provided to OTA, January 18, 1991.

262. Petersdorf, R.G., Adams, R.D., Braunwald, E., et al. (eds.), ***Principles of Internal Medicine,*** 10th ed. vol. 1 & vol. ***2 (New*** York, NY: McGraw-Hill Book Co., 1983).

263. Plasse, T., Ohnuma, T., Bruckner, H., et al., "Portable Infusion Pumps in Ambulatory Cancer Chemotherapy, " ***Cancer*** 50:27-31, ***1982.***

264. Plumer, **A. L., and Cosentino, F.** (eds.), ***Principles and Practice of Intravenous Therapy (New*** York, NY: Little, Brown and Co., 1987).

265. Poniatowski, B. C., "Continuous Subcutaneous Infusions for Pain Control," ***Journal of Intravenous Nursing*** 14(1):30-35, ***1991.***

266. **Poretz, D. M., "Home Management of Antibiotic Therapy," *Current Clinical Topics in Infectious Disease*** 10:27-42, ***1989.***

267. **Poretz, D. M., Eron, L.J., Goldenberg, R. I., et al., "Intravenous Antibiotic Therapy in an Outpatient Setting," *Journal of the American Medical Association*** 248(3):336-339, ***1982.***

268. Poretz, D.M., Woolard, D., Eron, L.J., et al., "Outpatient Use of Ceftriaxone: A Cost-Benefit *Analysis,'' AmericanJournal ofMedicine* 77(Suppl. *4C):77-83, 1984.*

269. Potter, M., Chief of Case Management, program Initiatives Branch, program Operations Division, Office of CHAMPUS, Office of the Assistant Secretary of Defense for Health Affairs, Office of the Secretary of Defense, Aurora, CO, personal communication, March 28, 1991.

270. Pozzi, M., and Peck, N., "An Option for the Patient With Chronic Osteomyelitis: Home Intravenous Antibiotic Therapy, ' ***Orthopedic Nursing*** 5(5):14, September/October 1986.

271. Prandoni, P., Lensing, A. W., Buller, H.R., et al., "Comparison of Subcutaneous Low-Molecular-Weight Heparin With Intravenous Standard Hepam in Proximal Deep-Vein Thrombosis,' *Lancet* 339(8791):441-445, 1992.

272. Prime, M.T., Vice President of Franchise Operations, O.P.T.I.O.N. Care, Inc., Chico, CA, personal communications, July 31, 1990 and April 3, 1991.

272a. Prospective Payment Assessment Commission, ***Medicare Prospective Payment and the American Health Care System, Report to the Congress*** (Washington, DC: U.S. Government Printing Office, June 1, 1989).

273. Prospective Payment Assessment Commission, ***Report and Recommendations to the Congress*** (Washington, DC: U.S. Government Printing Office, March 1, 1991).

274. Prospective Payment Assessment Commission, ***Rural Hospitals Under Medicare's Prospective Payment System Congressional Report*** (Washington, **DC: U.S. Government Printing Office, October 1991).**

275. Prudential-Bache **Securities, Inc., New *England Critical Care Company Report (New*** York, NY: Prudential-Bache Securities, Inc., 1990).

276. Quebbeman, E.J., Hamid, A.A.R., Hoffman, N.E., et al., "Stability of Fluorouracil in Plastic Containers Used for Continuous Infusion at Home," *American Journal of Hospital Pharmacy 41(6):* 1153-1156, June 1984.

277. Rapp, R.P. and Bivins, B., "Cost Effectiveness of In-line Filters in the Era of DRGs," ***Infections in Medicine*** 1(2):66-72, November/December 1984.

278. Rehm, **S. J., and Weinstein, A. J., "Home Intravenous Therapy: A Team Approach,'** *Annals of Internal Medicine* 99:388-392, *1983.*

279. Relrnan, A. S., "Antitrust Law and the **Physician Entrepreneur,' New *England Journal of Medicine*** 313(14):884-885, **October 3, 1985.**

280. Relman, **A. S., "Dealing With Conflicts of Interest,''** *New England Journal of Medicine 313(12):749-751,* September 19, 1985.

281. Rice, T., and **McCall, N., "Changes in Medicare Reimbursement in Colorado: Impact on Physicians' Economic Behavior,'** *Health Care Financing Review 3(4), 1982.*

282. **Richards, D., "Technology Review** Interleukin-2 **Update,"** *Health Business* 6(9):1T, *1991.*

283. Ritter, **H.TM., "Evaluating and Selecting General Purpose Infusion Pumps,"** *Journal of Intravenous Nursing* 13(3):156-161, *1990.*

284. **Robinson, B. E., and Quesenberry, P.J., ''Hematopoietic Growth Factors: Overview and Clinical Applications,"** *American Journal of Medical Science* 300(4):237-244, *1990.*

285. Roe, W., Gong, J., **Anderson, M., et al., "The Safety, Effectiveness and Cost-Effectiveness of Home Intravenous Antibiotic Therapy for the Elderly: New Findings and Opportunities for Public Policy,' unpublished manuscript prepared for Health Industry Manufacturers Association, Washington, DC, September 10,1987.**

286. Rogers, A.G., "Home Intravenous Opoid Therapy in a Toddler With Advanced Cancer," *Journal of Pain and Symptom Management* 4(4):230-231, *1989.*

287. **Rooney, A., Director, Home Care Accreditation, Joint Commission on Accreditation of** Healthcare **Organizations, Oakbrook Terrace, IL, personal communication, September 5, 1991.**

288. Rucker, **B. B., and Holmstedt, K. A.,** *The Home Infusion Therapy Industry (New* **York, NY:** Hambrecht **& Quist, Inc., April 1984).**

289. Rucker, B. B., and Witter, S.T., *The Home Drug Delivery Industry: An Outlook (New* York, NY: **Harnbrecht & Quist, Inc., January 1987).**

290. Rucker, R.W., and Harrison, G.W., "Outpatient Intravenous Medications in the Management of Cystic Fibrosis," *Pediatrics* 54:358-360, *1974.*

291, **Rutherford, C.,** CRNI, **MidAmericaHospital, Overland** Park, **KS, personal communication, February 13, 1991.**

292. Sabatino, C., ''Homecare Quality: Putting Public Accountability to the Test," *Generations 13(1):12-16, 1989.*

293. ***Salive,*** **M. E.,** Mayfield, **J. A., and Weissman, N. W., "Patient Outcomes Research Teams and the Agency for Health Care Policy and Research,"** *Health Services Research* 25(5):697-708, **Decem**ber 1990.

294. Samuels, **B.L., Vogelzang, N.J., Ruane, M., et al., "Continuous Venous Infusion of** Doxorubicin **in Advanced Sarcomas,"** *Cancer Treatment Report* 71:971-972, *1987.*

295. Scara, L., Director of Pharmacy (and Member of the New Jersey State Board of Pharmacy), Meadowlands Hospital Medical Center, Seacaucus, NJ, personal communication, March 29, 1991.

296. Schad, R.F., and Lucarotti, R. L., "Patient-Teaching Program for Home Intravenous Antimicrobial Therapy," *American Journal of Hospital Pharmacy* 43:372-375, February 1986.

297. Schlag, P., "Continuous Cancer Chemotherapy," *International Journal of Technology Assessment and Health Care* 1(2):343-351, *1985.*

298. Schlenker, R.E., and Shaughnessy, P.W., "Swing-Bed Hospital Cost and Reimbursement," *Inquiry* 26:508-521, *1989.*

299. Schmidt, G.M., Horak, D.A., Niland, J. C., et al., ''A Randomized, Controlled Trial of Prophylactic Ganciclovir for Cytomegalovirus Pulmonary Infection in Recipients of Allogeneic Bone Marrow Transplants,' New *England Journal of Medicine* 324(15):1005-1011, *1991.*

300. Schneider, D.P., Fries, B.E., Foley, W.J., et al., ''Case Mix for Nursing Home Payment: Resource Utilization Groups, Version II," *Health Care Financing Review 1988* **Annual Supplement, pp. 39-52, 1988.**

301. Scrip, "Delivery Systems and Improved Therapy," *Scrip* 1634:27, *1991.*

302. Scrip, "MultipleI ndications Sought for S-Plough/ Sandoz' GM-CSF," *Scrip* 1636:26-27, *1991.*

303. scrip, "NOVO Nordisk's Nasal Insulin Trial," *Scrip 1632, 1991.*

304. scrip, "Roche's Oral Insulin Research," *Scrip* 1685:25, *1991.*

305. Scrip, ''Transdermal Fentanyl Launched," *Scrip* 1623:24, *1991.*

307. Shaw, S. H., and Roesch, E. D., *Home Infusion Therapy Industry: Robust Growth Prospects (New* York, NY: Prudential-Bache Securities, Inc., Jan. 20, 1988).

308. Shils, M., Chairman of the Advisory Board for the Registry of Patients on Home Total Parenteral Nutrition, New York Academy of Medicine, New York, NY, personal communication, August 1983.

309. Shuda, M.R., "Unwanted Effects and Complications of Epidural Morphine Administration," *Parenterals* 5(2):2-3, April/May 1987.

310. Silverman, H.A., ''Swing-bed Services Under the Medicare Program, 1984-1987," *Health Care Financing Review,* pp. 399406, spring 1990.

311. Simmons, B.P., Hooton, T.M., Wong, E. S., et al., ''Guidelines for Prevention of Intravascular Infections,' *American Journal of Infection Control* 3:61-72, *1982.*

312. Simmons, **B.P., Trusler, M., Roccaforte, J., et al., "Infection Control for Home Health,"** *Infectious Control of Hospital Epidemiology* 11:362-370, *1990.*

313. Sloan, F., Mitchell, J., and Cromwell, J., "Physician Participation in State Medicaid Programs, " *Journal of Human Resources* 13(Suppl.):211-245, *1979.*

314. Sloan, F.A., Morrisey, M.A., and Valvona, J., "The Effects of the Medicare Prospective Payment System on Hospital Cost Containment: An Early Appraisal," *The Milbank Quarterly* 66(2):191-*220, 1988.*

315. Sloan, F., and Steinwald, B., ''Physician Participation in Health Insurance Plans: Evidence From Blue Shield," *Journal of Human Resources* 13(spring): 237-263, 1979.

316. Smith, D.E., "Spinal Opioids in the Home and Hospice Setting," *Journal of Pain and Symptom Management* 5(3):175-182, *1990.*

317. Smith, P,W., "Antimicrobial Therapy in Special Situation, Including Extended Care Facilities and Outpatient Setting," *American Journal of Infection Control* 17:316-322, *1989.*

318. Sorensen, R.U., Kallick, M.D., and Berger, M., ''Home Treatment of Antibody-Deficiency Syndromes With Intravenous Immune Globulin," *Journal of Allergy and Clinical Immunology* 80:810-815, *1987.*

319. Speight, T.M. *(ed.), Avery 'sDrug Treatment (New* Zealand: ADIS Press Limited, **1987).**

320. Stafford, C.T., "Adverse Drug Reactions," *Medical Times* 116(2):31-42, *1988.*

321. State of Florida Health Care Cost Containment Board, *Joint Ventures Among Health Care Providers in Florida,* vol. II (draft) (Tallahassee, FL: Florida HCCCB, August 1991).

322. Stecy, P., and Gunnar, R.M., "Is Intermittent Dobutamine Infusion Useful in the Treatment of Patients With Refractory Congestive Heart Failure?" *Cardiovascular Clinical* 21(1):277-289, *1990.*

323. Stiehm, E.R., "New Uses for Intravenous Immune Globulin" [letter], *New England Journal of Medicine* 325(2):123-125, *1991.*

324. Stiver, H.G., Telford, G. O., Mossey, J.M., et al., "Intravenous Antibiotic Therapy at Home," *Annals of Internal Medicine* 89(Part 1):690-693, *1978.*

325. Stiver, H.G., Trosky, S.K., Cote, D.D., et al., "Self-Administration of Intravenous Antibiotics: an Efficient, Cost-Effective Home Care Program," *CMA Journal* 127:207-211, *1982.*

326. St. Marie, B., "Administration of Intraspinal Analgesia in the Home Care Setting," *Journal of Intravenous Nursing* 12(3):164-168, May-June 1989.

327. St. Marie, B., and Hendrickson, K., ''Intraspinal Narcotic Insutions for Terminal Cancer Pain," *Journal of Intravenous Nursing* 11(3):161-163, *1988.*

328. Strandvik, B., Hjelte, L., and Widen, B., "Home Intravenous Antibiotic Treatment in Cystic Fibrosis," *Scandinavian Journal of Gastroenterology* 23(Suppl.143):119-120, *1988.*

329. Strickland, D.A., "Pharmacists Encroaching on Care," *Medical World News* 32(1):42, **January 1991.**

330. **Strumpfer, A. L., "Lower Incidence of Peripheral Catheter Complications by the Use of Elastomeric Hydrogel Catheters in Home Intravenous Therapy** *Patients,' 'Journal of Intravenous Nursing 14(4):261-267,* July-August 1991.

331. Sullivan, M., "IV Antibiotic Acquisition Costs," *OPIVATA Newsletter* 1(3):2, *1990.*

332. ***Sun* Belt Pharmacare, San Antonio, TX, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, January 25, 1991.**

333. **Sutton, S., Senior Vice President for Medicare Services, Kimberly Quality Care, Boston, MA, personal communication, January 18, 1991.**

334. **Swan, J.H., Barrington, C., and Grant, L.A., 'State Medicaid Reimbursement for Nursing Homes,** *1978-86, ''Health Care Financing Review 9(3):33-50.*

335. Swenson, J.P., "Training Patients to Administer Intravenous Anitbiotics at Home,' *'American Journal of Hospital Pharmacy* 38:1480-1483,1981.

336. **Talbott, J.A., Hale, R.E., and Yudofsky, S.C. (eds.),** ***The American Psychiatric Press Textbook of Psychiatry*** (Washington, DC: American Psychiatric Press, 1988).

337. Taylor, N., Hutchison, E., Milliken, W., et al., "Comparison of Normal Versus Heparinized Saline for Flushing Infusion Devices," ***Journal of Nursing Quality Assurance*** 3(4):49-55, **August 1989.**

338. **Terry, L.J., and Grigsby, S.F., "Visiting Nurse Home Pharmacy: A Successful Home Pharmacy Venture,"** *Caring,* May **1990,** pp. 28-32.

339. Terry, R. D., and Katzman, R., "Senile Dementia of the Alzheimer Type," ***Annals of Neurology*** 14(5):497-506, November 1983.

340. Tice, A.D., "An Office Model of Outpatient Parenteral Antibiotic Therapy,' *Reviews of Infectious Diseases* 13(Suppl. *2):* S184-188, *1991.*

341. **Tice, A.D., ''OPIVAT—A Fifteen Month Review,"** *OPIVATA Newsletter* 1(5):2, *1990.*

342. **Todd, J., Executive Vice President, American Medical Association, Chicago, IL, personal communication, Sept. 11, 1991.**

343. **Total Pharmaceutical Care, Inc., Torrance, CA, information provided to the Office of Technology Assessment, U.S. Congress, Washington, DC, January 31, 1991.**

344, **Tresch, D. D., Simpson, W. M., and Burton, J. R., "Relationship of Long-Term and Acute-Care** Facilities," ***Journal of the American Geriatrics Society 33(12): 819-826,*** December 1985.

345. **Turco,** S., "Clinical Use of Parenterals," ***Parenterals*** 1:4, *1983.*

346. **Turco,** S., **"Infusion Phlebitis: A Review of the Literature,"** *Parenterals* 5:1-8, *1987.*

347. University Medical Center Home Health Services, Tucson, AZ, site visit by OTA staff, May 2, 1991.

348. Unverferth, D.V., Magorian, R.D., Altschult, R., et. al., 'The Hemodynamic and Metabolic Advantages Gained by a Three-Day Infusion of Dobutamine in Patients With Congestive Cardiomyopathy," ***American Heart Journal*** 106(1 Part 1):29-34, 1983.

349. Unverferth, D. V., Magorian, R. D., Lewis, R. P., et. al., ''Long-term Benefit of Dobutamine in Patients With Congestive Cardiomyopathy," ***American Heart Journal*** 100(5):622-630, *1980.*

350. U.S. Congress, Library of Congress, Congressional Research Service, ***The Peer Review Organization (PRO) Program,*** report to the Senate Committee on Finance, U.S. Congress, 87-258 EPW (Washington, DC: U.S. Government Printing Office, 1987).

351. U.S. Congress, General Accounting Office, ***Medicare: Assuring the Quality of Home Health Services,*** GAO Report No. HRD-90-7 (Washington, DC: U.S. General Accounting Office, October 1989).

352. U.S. Congress, General Accounting Office, ***Health Care: Limited State Efforts To Assure Quality of Care Outside Hospitals,*** GAO Report No. HRD-90-53 (Washington, DC: U.S. General Accounting Office, January 1990).

353. U.S. Congress, General Accounting Office, ***Medicare: Comparison of Two Methods of Computing Home Health Care Cost Limits, GAOfHRD-90-167*** (Washington, DC: U.S. Government Printing Office, September 1990).

354. U.S. Congress, General Accounting Office, ***Off Label Drugs—Initial Results of a National Survey,*** GAO/PEMD-91-12BR **(Washington, DC: February 1991).**

355. **U.S. Congress, General Accounting Office,** ***Medicare: PRO Review Does Not Assure Quality of Care Provided by Risk HMOs,*** GAO **Report No.** HRD-91-48 **(Washington, DC: U.S. General Accounting Office, March 1991).**

356. **U.S. Congress, House Committee on Ways and Means, Subcommittee on Health and the Subcommittee on Oversight, issues Related to Physician "Self Referrals." Statement of Richard P. Kusserow, Inspector General, U.S. Department of Health and Human Services, hearings on H.R. 939, June 1, 1989, p. 125.**

357. U.S. Congress, Library of Congress, Congressional Research Service, ''The Peer Review Organization (PRO) Program," report to the Senate Committee on Finance, U.S. Congress, 87-258 EPW (Washington, DC: U.S. Government Printing Office, 1987).

358. U.S. Congress, Library of Congress, Congressional Research Service, "Medicaid: FY1991 Budget and Child Health Initiatives,' prepared by Melvina Ford, Education and Public Welfare Division, Washington, DC, February 1990.

359. U.S. Congress, Office of Technology Assessment, ***Medical Technology and Costs of The Medicare Program,*** OTA-H-227 (Washington, DC: U.S. Government Printing Office, July 1984).

360. U.S. Congress, Office of Technology Assessment, ***Federal Policies and the Medical Devices Industry,*** OTA-H-230 (Washington, DC: U.S. Government Printing Office, October 1984).

361. U.S. Congress, Office of Technology Assessment, ***Technology and Aging in America,*** Report No. BA-264(Washington, DC: U.S. Government Printing Office, 1985).

362. U.S. Congress, Office of Technology Assessment, ***Life Sustaining Technologies and the Elderly, OTA-BA-306*** (Washington, DC: U.S. Government Printing Office, July 1987).

363. U.S. Congress, Office of Technology Assessment, ***The Quality of Medical Care: Information for Consumers,*** OTA-H-386 (Washington, DC: U.S. Government Printing Office, June 1988).

364. U.S. Congress, Office of Technology Assessment, site visits and discussions with providers, insurers, and representative orgainizations, 1990-91 (see app. A for more detail).

365. U.S. Congress, Office of Technology Assessment, survey of Medicare Part B carriers regarding coverage of and payment for drugs used in infusion pumps under the durable medical equipment (DME) benefit. Conducted under contract to OTA by Julia T. Ostrowsky, February 1991.

366. U.S. Congress, Office of Technology Assesment, update of McAllister survey of State regulation of home infusion pharmacy, March 1991 (see J.C. McAllister III and S.M. Davis, 'State Regulations for Home IV Therapy" [letter], ***American Journal of Hospital Pharmacy*** 46:1545-1546, **August 1989).**

367. U.S. Congress, Office of Technology Assessment, confidential information provided to OTA, 1990-91.

368. U.S. Congress, Office of Technology Assessment, conversations with staff from the Health Care Financing Administration, Office of Coverage Policy and Bureau of Policy Development, Sept. 27, 1990.

369. U.S. Department of Commerce, Bureau of the Census, ***Health Insurance Coverage 1986-88,*** Nelson, C., and Short, K. (eds.), Series P-70, No. 17 (Washington, DC: U.S. Government Printing Office, 1990).

370. U.S. Department of Health and Human Services, Health Care Financing Administration, Baltimore, MD, ***State Operations Manual: Provider Certification*** (advance copy of final issuance), Transmittal no. 245, March 1991.

371. U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, Office of Statistics and Data Management, ***Descriptive Statistics Report No. 6: 1989 BMAD Data,*** Section 5: National Summaries by Procedure, Services only for National (Baltimore, MD: BDMS, February 4, 1991).

372. U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, Office of Statistics and Data Management, Rockville, MD, ***Medicare Home Health Agency Licensure Statistics,*** provided to OTA in April 1991.

373. U.S. Department of Health and Human Services, Health Care Financing Administration, Division of Intergovernmental Affairs, ***Medicaid Services State by State,*** HCFA Pub. No. 02155-90, October 1, 1990.

374. U.S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, ***Medicare Peer Review Organization Manual,*** DHHS Pub. No. PB88-954099 (Springfield, VA: U.S. Department of Health and Human Services, 1988).

375. U.S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, MD, ***Generic Quality Screens—Home Health Agency,*** **August 1989.**

376. U.S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, MD, *Guidelines for PRO Review of Home IV Drug Therapy Services [Draft]*, September 1989.

377. U.S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, MD, ***Home IV Drug Therapy Quality Screens [Draft],*** September 1989.

378. U.S. Department of Health and Human Services, Health Care Financing Administration, ***Medicare Carrier's Manual,*** 1991.

379. U.S. Department of Health and Human Services, Health Care Financing Administration, ***Medicare Intermediaries Manual,*** 1991.

380. U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstrations, ***Competitive Bidding for Health Care Services,*** HCFA Pub. No. 03227 (Baltimore, MD: HCFA, August 1986).

381. U.S. Department of Health and Human Services, Health Care Financing Adrninistration, 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).

382. U.S. Department of Health and Human Services, Office of the Secretary, ***Secretary's Commission on Nursing Final Report*** vol. I (Washington, DC: USDHHS, December 1988).

383. U.S. Department of Health and Human Services, Office of Inspector General, ***Financial Arrangements Between Physicians and Health Care Businesses,*** prepared by Richard Kusserow, May 1989.

384. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Health Statistics, ***Nursing Home Characteristics: 1986 Inventory of Long-Tern Care Places,*** Vital and Health Statistics, Series 14, No. 33 (DHHS publication no. (PHS) 89-1828), Washington, DC.

385. U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Bureau of Health Professions, Office of Data Analysis and Management, ***Seventh Report to the President and Congress on the Status of Health Personnel in the United States,*** DHHS. Pub. No. HRS-P-OD-90-1 (Washington, DC: U.S. Government Printing Office, March 1990).

385a. U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Bureau of Health Resources Development, Division of Organ Transplantation, ***Annual Report on the U.S. Scientific Registry for Organ transplantation and the Procurement and Transplantation Network, 1988 and 1989,*** Contract Nos. 240-87-0069 and 240-87-0063 (Washington, DC: HRSA, 1990).

386. U.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, ***Vital and Health Statistics,*** Health Statistics on Older Persons, United States, 1986, Series 3, No. 25, DHHS Pub. No. (PHS) 87-1409 (Washington, DC: U.S. Government Printing Office, June 1987).

387. U.S. Department of Health, Education, and Welfare, Public Health Service, ***NIAID Task Force Report on Asthma and the Other Allergic Diseases,*** National Institute of Health Publication No. 79-387, May, 1979, p.501.

388. U.S. v. Kats, 871 F. 2d 105 (9th Cir. 1989).

389. Van Buren, L., Administrator, Home Health Agency/ Hospice, Kaiser Permanence, Portland, OR, personal communication, Nov. 27, 1990.

390. Visiting Nurses Association of Washington, DC, Washington, DC, site visit by OTA staff, December 14, 1990.

391. Vital Care, Inc., Livingston, AL, site visit by OTA staff, November 2, 1990.

392. Watson, L., "The Home IV Market Races On," ***Homecare 13(12): 60,62,75,*** December 1991.

393. ***Webster' sNinthNewCollegiate Dictionary*** (Springfield, MA: Merriam-Webster Inc., 1985).

394. Weeks, J.D., Tierney, M.R., and Weinstein, M. C., "Cost Effectiveness of Prophylactic Intravenous Immune Globulin in Chronic Lymphocytic Leukemia,'' ***New EnglandJournal of Medicine 325(2):81-86, 1991.***

395. Weiner, J.P., 'Assuring Quality of Care in HMOs: Past Lessons, Present Challenges and Future Directions," ***Group Health Journal*** Spring:10-27, 1986.

396. Wesenberg, F., Anker, C., Somrnerschild, H., et al., "Central Venous Catheter With Subcutaneous Injection Port (Port-A-Cath): Clinical Experience With Children," ***Pediatric Hematology and Oncology*** 4(2):137-143, 1987.

397. West, J., ***Physiological Basis for Medical Practice,*** 11th ed. (Baltimore, MD: Williams and Wilkins, 1985).

398. Wetmore,N., "Extravasation—TheD readed Complication,' ***Journal of the National Infusion Therapy Association*** 8(1):47,1985.

399. Wilensky, G., Administrator, Health Care Financing Admini'stration, Baltimore, MD, "Statement," ***DME Fraud and Abuse,*** hearing before the Senate Committee on the Budget, House of Representatives, U.S. Congress, July 25, 1991.

400. Winter, R.J.D., Deacock, S.J., George, R.J.D., et al., "Self-administered Home Intravenous Antibiotic Therapy in Bronchiectasis and Adult Cystic Fibrosis," ***Lancet***, pp. 1338, 1984.

401. World Health Organization, ***Cancer Pain Relief*** (Geneva, Switzerland: WHO, 1986).

402. Wyremski, S., ABEL Health Management Services, Inc., Great Neck, NY, personal communication, January 18, 1991.