

Chapter 4

# THE HOME DRUG INFUSION INDUSTRY

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## THE HOME DRUG INFUSION INDUSTRY

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### Overview

#### *Introduction*

The home infusion industry<sup>1</sup> 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)<sup>2</sup> (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.

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<sup>1</sup> Most providers in the home infusion industry offer parenteral nutrition as well as drug infusion therapies.

<sup>2</sup> 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).<sup>3</sup>

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 nonhospital 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 sophisti-

cated 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,

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<sup>3</sup> 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 specified 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)<sup>4</sup> 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

<sup>4</sup>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 day, 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<sup>5</sup> 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<sup>6</sup> 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-

<sup>5</sup>The survey was mailed to 1,983 hospitals with home care programs in May 1990. The response rate was 41 percent (197).

<sup>6</sup>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 a broad 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).<sup>7</sup>

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 'corner drug

<sup>7</sup>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 voluntary . . . . .	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 <sup>b</sup> . . . . .	178	61		NA
<b>Total . . . . .</b>	<b>2,329</b>	<b>2,973</b>	<b>5,721</b>	<b>5,721</b>

NOTE: NA - not applicable. See footnote b.

<sup>a</sup>A voluntary organization (e.g., a visiting nurses association) that receives some operational funding from government sources.

<sup>b</sup>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 prac-

tice 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 parenteral 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.

**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.

**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.)

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, home-bound 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 Houston, 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.

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

**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 ceftioxone for the treatment of osteomyelitis, 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.J. Tice, "An Office Model of Outpatient Parenteral Antibiotic Therapy," *Reviews of Infectious Diseases* 13(Suppl. 2):S184-188, 1991.

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 Foundation 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<sup>a</sup>**

Company	1988	1991
Caremark . . . . .	37.3%	29.3%
New England Critical Care <sup>b</sup> . . . . .	4.1	7.1
Home Nutritional Services . . . . .	4.0	4.2
HMSS . . . . .	3.0	4.7
National Medical Care <sup>c</sup> . . . . .	2.5	4.2
Care Plus <sup>b</sup> . . . . .	1.9	2.4
Continental Affiliates . . . . .	2.8	2.2
T <sup>d</sup> . . . . .	2.8	2.7
Other . . . . .	41.9	43.3

<sup>a</sup>Includes revenues from total parenteral nutrition.  
<sup>b</sup>In February 1991, after these projections were made, New England Critical Care merged with Care Plus to form Critical Care of America, Inc.  
<sup>c</sup>Includes revenue projections for Infusion Care, acquired by National Medical Care in January 1989.  
<sup>d</sup>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,<sup>8</sup> served 2,941 home infusion therapy clients<sup>9</sup> 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).

<sup>8</sup>As of January 1990, 170 of these branches offered full-service home infusion therapy services (333).  
<sup>9</sup>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 infusion 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 ciprofloxacin, 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 irritation 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.<sup>10</sup>

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 1-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).

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<sup>10</sup> 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).