Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE HOME INFUSION THERAPY

SEPTEMBER 1993 OEI-02-92-00420

EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection is to describe the Medicare home infusion industry including reimbursement trends, coverage, company characteristics and physician financial arrangements.

BACKGROUND

Home infusion therapy, one of the fastest growing segments of home health care, has made it possible for increasingly sophisticated treatments to be given in the home. These include enteral and parenteral nutrition and other therapies such as intravenous antibiotics and chemotherapy.

According to a May 1992 Office of Technology Assessment (OTA) report, a few large companies dominate the national market. The remaining companies include midsized firms with strong regional markets and numerous small firms with local pharmacists, home health agencies, hospitals and nursing homes increasingly entering the market.

Medicare patients appear to be a small part of the total home infusion market. While Medicare coverage is clearly defined for enteral and parenteral nutrition, other home infusion therapy services are covered in a fragmented way. Although Medicare covers drugs and biologicals when used with an infusion pump, carriers are given discretion in implementing this coverage.

Over the last decade, both Congress and the Office of Inspector General (OIG) have had concerns about physician financial arrangements with medical entities, including home infusion companies. The Omnibus Budget Reconciliation Act of 1993 generally prohibits payment by Medicare and Medicaid for services performed by clinical laboratories, durable medical equipment providers, home health agencies, and suppliers of parenteral and enteral nutrition when such services are ordered by a physician who has a financial relationship with the supplier.

METHODOLOGY

We gathered and analyzed four sets of data relevant to the four parts of the study's purpose. (1) To estimate recent trends in Medicare reimbursements for home infusion services, we reviewed Health Care Financing Administration (HCFA) data on allowed charges for services and supplies representing home infusion charges in 1990 and 1991. (2) To describe Medicare coverage for home infusion services, we looked at Medicare coverage guidelines, reviewed existing literature, spoke to various respondents knowledgeable in the industry, and analyzed carrier payment data. (3) To describe home infusion companies serving Medicare patients, we drew a random sample of 200 beneficiaries who had pumps billed in 1991 and identified the companies which provided these pumps. From these companies, we identified and

interviewed 57 which provide infusion therapy in the home. (4) To describe the nature and extent of physician financial arrangements, we interviewed 30 representatives of 30 randomly selected home infusion companies, three of which were independent locations of the same company; a non-random sample of 28 physicians; and 17 other respondents representing 11 professional organizations and 6 referring agencies.

FINDINGS

Medicare Payments for Home Infusion Therapy are Rising Rapidly

The number of Medicare beneficiaries who received infusion services in the home grew by 91 percent from 14,500 in 1990 to 27,700 in 1991. Estimated total allowed Medicare charges for infusion therapy in the home leapt 213 percent, from $61 million to $191 million. The average allowed charges annually per Medicare beneficiary jumped 63 percent, from $4243 to $6923.

Carriers Are Not Uniformly Covering Home Infusion Therapy

The OTA study, an analysis of carrier payments, and comments of study respondents indicate great variability in coverage policy among Medicare carriers. While 17 carriers have policies to cover only the drugs and conditions specified by HCFA, other carriers cover not only these, but a wide variety of others as well.

Physician Ownership and Other Financial Arrangements Are Common

Of the 30 infusion company respondents in our sample, five (17 percent) report having physician owners. Ten (33 percent) of the sample infusion company respondents report having some other sort of financial or business arrangement with one or more physicians. Such arrangements are complex and it is difficult to determine what effect, if any, they may have on Medicare. In regard to both the physician ownership and other financial arrangements discussed in this report, we did not have sufficient data to determine the effects that OBRA 1993 would have on Medicare payment for services ordered by physicians with the financial arrangements we found.

Perceptions of company, physician and other respondents as to the extent of physician arrangements differ from physicians' and companies' reported behavior, suggesting that the full nature and extent of such arrangements are unclear. Most company respondents, for example, believe physician arrangements to be very or somewhat common, even though over half report having no such arrangements.

In contrast to the infusion industry in general, which is dominated by a few large firms, smaller companies are providing home infusion to Medicare patients.

RECOMMENDATIONS

In light of our findings, we believe that HCFA should: 1) monitor spending to better identify trends; 2) provide more specific coverage guidelines; and 3) collect ownership and compensation information on form HCFA-192, use this information to monitor referral and utilization patterns, and refer suspected cases of abuse to the Office of Inspector General.

COMMENTS

Written comments received from HCFA and verbal comments received from OTA concur with the recommendations of this report. Suggestions for changes in the wording, clarifications of the text and any technical changes have for the most part been incorporated into the final report. The actual comments received from HCFA are in Appendix D.

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INTRODUCTION

PURPOSE

The purpose of this inspection is to describe the Medicare home infusion industry including reimbursement trends, coverage, company characteristics and physician financial arrangements.

BACKGROUND

Home infusion therapy, one of the fastest growing segments of home health care, has made it possible for increasingly sophisticated treatment to be given in the home, including care previously available only in a hospital. It offers a variety of medical treatments. They include enteral nutrition, which provides the patient with liquid nourishment through a tube inserted into the stomach, either directly through the skin or through a naso-gastric tube; parenteral nutrition which provides liquid nourishment intravenously; and antibiotics administered intravenously when a drug cannot be administered orally or by injection. Chemotherapy, pain management, blood transfusions, hydration therapy, and human growth hormones are other treatments. For the purposes of this study, nutrition therapy refers to enteral and parenteral services, while the remaining services are referred to as other therapies.

Components of home infusion include: equipment (such as pumps and poles); supplies (such as dressing supplies and infusion sets); nutrients, drugs and pharmacy services; nursing services; physician services; laboratory services; and patient assessment and training.

A significant development in home infusion has been the advent of the portable, electronic pump used to administer the drug. It allows the flow of the drug to be controlled, does not require the constant care of a nurse and helps ensure greater patient safety.

The Home Infusion Therapy Industry

The industry includes various players: home infusion companies, home health agencies, visiting nurse services, pharmacies and durable medical equipment (DME) companies. The patient's attending physician usually coordinates the care.

According to a May 1992 Office of Technology Assessment (OTA) report, entitled Home Drug Infusion Therapy Under Medicare, a few large companies dominate the national market. The remaining companies include midsized companies with strong regional markets and numerous small firms. Entering the business are a growing number of community pharmacists, as evidenced by the growth of pharmacy franchise companies, as well as home health agencies, hospitals and nursing homes.

Medicare patients appear to be a small part of the total market. The OTA estimated that roughly 20,000 to 35,000 elderly were receiving home drug infusion therapy in 1991, about 10 to 15 percent of all home drug infusion patients. The National Alliance for Infusion Therapy (NAIT), which represents nineteen home infusion companies, including many of the larger firms, estimates that between 11 to 15 percent of its members' patients are on Medicare. It also reports that most of its members' home infusion patients receive antibiotic therapy and enteral nutrition.

The January 1991 issue of Homecare Magazine listed the top ten infusion companies by sales volume. The number one company, Caremark, had sales of $625 million and operated in 120 locations. The next nine companies ranged from $83 million in sales to $17.2 million. These companies provide both nutrition and other therapies.

Besides providing the therapy itself (including the necessary equipment and drugs), the large companies offer clinical pharmacy and nursing services. The more traditional DME companies primarily furnish equipment and supplies. Companies may also have patient advocates on staff who meet with patients to coordinate their care, to answer questions and to address their concerns. One large firm has home patient representatives who coordinate the services of the physician and company staff, such as nurses and pharmacists; they also monitor patient compliance.

Medicare Coverage of Home Infusion Services

Medicare coverage of infusion services provided by companies to patients in their homes varies depending on the type of service. Claims for these services are reimbursed by Medicare Part B carriers, the Health Care Financing Administration (HCFA) contractors who are responsible for paying Part B claims.

Nutrition therapy coverage is clearly defined in the Medicare Carriers Manual (MCM), Section 2130, which discusses home enteral and parenteral nutrition in the context of prosthetic devices when ordered by a physician. It states, "Accessories and/or supplies which are used directly with an enteral or parenteral device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device are covered under the prosthetic device benefit..." Medicare allows nutrition therapy to be reimbursed for patients at home or in a nursing facility, including a skilled nursing facility, when the products are provided by an outside supplier who bills the Medicare carrier directly.

As noted in Medicare Part B MCM Section 2100.5, Medicare covers home infusion therapy primarily through its DME benefit. Infusion pumps are covered as equipment capable of withstanding repeated use when "medically necessary to ameliorate illness or injury or to improve functioning of a malformed body part." Medical supplies and accessories necessary for the proper functioning of the equipment are also covered. This includes tubing, needles and alcohol swabs, and also drugs and biologicals that must be put directly into the equipment to assure proper functioning.

Although Medicare covers drugs and biologicals when used with an infusion pump, the carrier is given discretion in implementing this coverage. The HCFA instructed carriers in the Medicare Coverage Issues Manual, Section 60-14 to cover the cost of external infusion pumps when used in the administration of: deferoxamine to treat acute iron poisoning and iron overload; heparin to treat thromboembolic disease and/or pulmonary embolism (in institutional settings only); chemotherapy for liver cancer patients and colorectal cancer patients who cannot or will not undergo surgical treatment; and morphine for intractable cancer pain. The manual goes on to say, "Other uses of external infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and the prescribed pump for the individual patient."

Other distinctions exist in Medicare's handling of nutrition and other infusion therapy services. Currently, only two carriers reimburse claims for all nutrition services, while all carriers pay for other infusion therapy. As of October 1993 four regional carriers will handle claims for all nutrition and other infusion therapy. This will allow them to make more consistent coverage decisions. All providers who supply DME will have to fill out a new Form HCFA-192, a "disclosure of ownership form," in order to obtain a new provider number needed to submit claims to the regional carriers.

Limits exist regarding the coverage of physician services relating to home infusion therapy. Medicare Part B covers physician hospital visits related to discharge and office visits, but does not ever cover physician administrative or telephone consultation services; direct contact with the patient is required in order for the physician to be reimbursed.

Lastly, Medicare also provides infusion services to homebound patients under its home health benefits. Home health agencies are reimbursed by Medicare intermediaries for nursing services, infusion equipment and supplies. Drugs and biologicals are, however, specifically excluded under the home health benefit. (We note that home infusion services provided by home health agencies are not within the scope of this study.)

Medicare Reimbursement of Home Infusion Services

In planning the study it was not possible to obtain Medicare reimbursement data for infusion patients treated in the home. Reasons for this difficulty include the large number of home infusion services and supplies and the fact that they are covered in a fragmented way. It thus became an objective of the study to obtain this reimbursement data, including trend information.

Concerns About Physician Financial Arrangements

Over the last decade, both Congress and the Office of Inspector General (OIG) have had increasing concerns about the proliferation of financial arrangements between physicians and various medical entities such as laboratories and DME companies. More recently, there has been an interest in the business of home infusion. For

instance, Modern Healthcare, November 1991, reported that one large company acknowledged paying $12 to $150 per week to hundreds of physicians under its Quality of Service Agreements. "Their reasoning for paying the fees is a common refrain in the homecare industry: The treatments for home care patients are getting more complex, and physicians should be paid for their part in managing that treatment." Notwithstanding this rationale, questions about the appropriateness of certain physician payments, and their budgetary impact, have prompted an increase in studies and regulations.

In June 1988, Congress mandated that the OIG conduct a study on ownership and compensation arrangements involving physicians and the health care entities. The study looked at independent clinical laboratories (ICL), independent physiological laboratories (IPL), and DME companies, but did not specifically look at home infusion companies. In a report published in May 1989, the OIG found that many physicians are owners of or have other financial relationships with health care businesses to which they refer patients. The study also found that those ICLs with physician arrangements had an increased utilization rate (45 percent more than other Medicare recipients) attributed to the patients of the physicians involved.

A January 1991 report by the State of Florida Health Care Cost Containment Board, entitled "Joint Ventures Among Health Care Providers in Florida", found that some types of physician-owned facilities had clearly increased costs, charges, and/or utilization, or were associated with greater access or quality problems, but the results varied depending on the type of facility. Infusion companies were not included in this study.

In its May 1992 report, the OTA states, "There is some evidence that physician ownership of health facilities is related to higher use of those facilities' services." They also report, "There is little consensus among physician associations regarding the acceptability of different ownership and financial arrangements."

The OIG has approached physician ownership and compensation arrangements as potential violations of the Medicare and Medicaid anti-kickback statute. This criminal provision is useful to the Federal health care programs as a means of limiting the influence of money on physicians' decisions regarding when and where to refer patients. In 1987, the Medicare and Medicaid Patient and Program Protection Act gave the OIG additional remedies for violations of the anti-kickback statute. In addition to criminal penalties, a violator may be subject to exclusion from participation in the Federal health care programs. The 1987 legislation also directed the OIG to develop the so-called "safe harbor" regulations, to clarify the types of arrangements or conduct that would not be subject to prosecution under the anti-kickback laws.

The Medicare Catastrophic Coverage Act of 1988 (later repealed) which would have explicitly covered home infusion would have prohibited payment for home drug infusion therapy services provided by a company in which the physician ordering the service had a financial interest. Based on the 1988 OIG study, Congress prohibited

Medicare payment for clinical laboratory services when ordered by a physician with a financial stake in the supplier. A number of States have banned or restricted physician "self-referrals," while other States permit self-referral as long as the physician and, in some cases, the referred entity disclose their financial relationship to patients.

The Omnibus Reconciliation Act (OBRA) of 1993 includes a provision which expands the current ban on payment for clinical laboratory services when ordered by a physician who has a financial relationship with the supplier. The expansion applies the prohibition on payment to a number of other services, including DME and parenteral and enteral nutrients, equipment and supplies, and prohibits payment by both Medicare and Medicaid. This expansion on the current ban for clinical laboratory services applies to referrals made after December 31, 1994.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Home infusion companies may voluntarily apply for accreditation from JCAHO as home care organizations. Standard GM.11.1 of JCAHO's Accreditation Manual for Home Care, 1993 edition, discusses physician involvement in the company. It states, "Professional experts, including physicians, are involved as appropriate in the development of patient/client care/service policies and procedures and the review and revision processes." The disclosure of ownership is on the application filled out by companies when applying for accreditation. If a physician or hospital owner is identified as an owner, they are required to disclose their ownership to any patients they refer to their own company for services.

METHODOLOGY

Overview

We gathered and analyzed four sets of data relevant to the four parts of the study's purpose. (1) To estimate recent trends in Medicare reimbursements for home infusion services, we reviewed HCFA data on allowed charges for services and supplies representing home infusion charges in 1990 and 1991. (2) To describe Medicare coverage for home infusion services, we looked at Medicare coverage guidelines, reviewed existing literature, spoke to various respondents knowledgeable in the industry, and analyzed carrier payment data. (3) To describe home infusion companies serving Medicare patients, we drew a random sample of 200 beneficiaries who had pumps billed in 1991 and identified the companies which provided these pumps. From these companies, we identified and interviewed 57 which provide infusion therapy in the home. (4) To describe the nature and extent of physician financial arrangements, we interviewed representatives of 30 randomly selected home infusion companies, three of which are independent locations of the same company, a non-random sample of 28 physicians, and 17 other respondents representing 11 professional organizations and 6 referring agencies.

HCFA Data on Allowed Charges

To estimate Medicare reimbursement for infusion services and to identify trends, we analyzed the data in a one percent random sample of the HCFA Common Working File (CWF), HCFA'S system for collecting carrier data nationally. These data consisted of total allowed Part B charges in 1990 and 1991 for both total infusion services and home infusion services. The allowed charges represent what Medicare considers reasonable for these services. The program pays 80 percent of allowed charges with beneficiary responsibility for coinsurance and deductibles. To estimate the payments for home infusion services, we developed a list of services and supplies representing a total of 121 billing codes which we believe, in the aggregate, capture these services. See Appendix A.

Medicare Coverage

In order to determine Medicare coverage of home infusion services we reviewed the Medicare Carrier's Manual (MCM) and various surveys and reports. Since we became aware of varying coverage of drugs and biologicals we gathered perceptions of people from agencies who referred patients for home infusion, infusion company representatives, members of professional organizations and physicians about carrier implementation of Medicare coverage guidelines. We also analyzed patterns of payments made by carriers in 1991 for infusion drugs including antibiotics, deferoxamine, some immunosuppressives and a chemotherapeutic agent, FUDR, used to treat liver cancer.

Infusion Company Characteristics

From HCFA's 1991 CWF we selected a random sample of 200 beneficiaries who had pumps billed (the major way that Medicare pays for home infusion therapy). See Appendix B. Twenty-one of these beneficiaries had pumps billed by more than one company. This should have given us the names of 221 infusion companies; we were able to identify 213 of them. We were unable to identify eight companies because the carrier did not supply us with this information. Seventy-eight were repeats of the same companies, thus giving us 135 different companies. We reached 128 of these companies; the remaining seven were defunct. The 128 includes some companies with several locations and represents a total of 117 firms.

When we started calling infusion companies to ask them about the home infusion therapy they provide, we soon realized that a substantial number of the companies only supplied nutrition therapy in nursing homes. Some companies were actually nursing homes. The companies which provide services only to nursing homes had minimal contact with the patients' physicians. In fact, the nursing homes, not the physician, referred patients to companies. We then screened all of the remaining companies in the sample and eliminated those which provided only nutrition therapy to nursing homes. Seventy-one companies were eliminated, leaving a total of 57 that provided infusion therapy in the home.

Physician Financial Arrangements

From the 57 companies we randomly selected a subsample of 30. Three of the 30 are locations of one larger company, but each location acts independently with its own manager, policies, and operations. We called representatives of the 30 and asked about the therapies they provide, any financial arrangements they may have with physicians and their views of the industry. We also requested samples of any contracts they may use with physicians. Five of the ten companies who told us about financial arrangements sent us examples of these contracts.

Additionally, we interviewed a non-random subsample of 28 of the 164 physicians who referred patients to the sample infusion companies about their relationships and involvement with home infusion companies and their general perceptions of the industry. We chose to conduct a convenience subsample when it became apparent that most physicians had limited experience with home infusion companies.

We also interviewed, by phone or in person, 11 principals of professional and trade organizations such as the National Alliance for Infusion Therapy (NAIT), the Outpatient Intravenous Infusion Therapy Association (OPIVITA), the American Academy of Home Care Physicians and the National Association for Home Care. Lastly, we interviewed a staff person from each of 6 referring agencies which included a home health agency, several hospitals and a nursing home. We asked about their experiences and their insights into physician financial arrangements with home infusion companies.

This inspection was conducted in accordance with the **Quality Standards for Inspections** issued by the President's Council on Integrity and Efficiency.

FINDINGS

MEDICARE PAYMENTS FOR HOME INFUSION THERAPY ARE RISING RAPIDLY

There has been a rapid increase in Medicare home infusion therapy reimbursement. The number of Medicare beneficiaries who receive infusion services in the home from infusion companies grew by 91 percent from 1990 to 1991 (see Table 1 below). From 1990 to 1991, estimated total allowed Medicare charges for infusion therapy in the home leapt 213 percent, from $61 million to $191 million.

The average allowed charges per Medicare beneficiary receiving infusion services in the home jumped 63 percent, from $4243 to $6923. One reason the average cost is growing so rapidly according to OTA is that "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."

TABLE 1: GROWTH OF INFUSION SERVICES UNDER MEDICARE PART B

	CY 1990	CY 1991	INCREASE
INFUSION SERVICES IN THE HOME:			
Estimated Number of beneficiaries	14,500	27,700	91%
Estimated Total $ allowed	$61 million	$191 million	213%
Estimated Average $ allowed	$4243	$6923	63%

CARRIERS ARE NOT UNIFORMLY COVERING HOME INFUSION THERAPY

Medicare carriers do not appear to be covering home infusion therapy in a uniform manner. We initially identified this problem during our review of the earlier mentioned OTA report and developed it further in discussions with OTA staff and industry experts. We also reviewed some additional OTA coverage data not published in the final report. Finally, comments volunteered by our study's respondents and our own data analysis further support the existence of this variable Medicare coverage.

The OTA study found great variability in coverage policy among Medicare carriers (see Appendix C). The OTA surveyed 43 carriers and found all had policies to cover the three drugs specified by HCFA in its Coverage Issues Manual: chemotherapy drugs for certain cancers, deferoxamine for acute iron poisoning or overload, and morphine for intractable cancer pain.

While 17 carriers had policies to cover only the drugs and conditions specified by HCFA, the other carriers had policies to cover not only those drugs, but a wide variety of other drugs as well. The OTA February 1991 data indicate, however, that many carriers did not have policies to cover drugs and conditions other than those specified by HCFA. Some examples of this disparity of coverage among the 43 carriers surveyed by OTA include:

- Twenty-five carriers cover cancer chemotherapy drugs for conditions other than those specified by HCFA.
- Thirteen carriers cover morphine for conditions other than those specified by HCFA.
- Fourteen carriers cover analgesics other than morphine if the patient is allergic to morphine; 10 cover other analgesics with few categorical restrictions.
- Fifteen carriers cover antibiotics for various chronic infections; two cover antibiotics only as an adjunct to cancer therapy.
- Two carriers cover hydration for patients already receiving other covered infusion therapy.

A few carriers even admitted covering certain drugs that are not administered through infusion pumps. The OTA report also states that, "Some carriers, for example, interpret the DME benefit to include even coverage for antibiotics administered by gravity drip. Other carriers almost never pay for any drug through this benefit."

The OTA found where carriers covered unspecified drugs and conditions, that coverage was sometimes limited to patients already receiving other infusion therapies. The OTA noted the present system promotes coverage for the sickest patients, while those healthier patients needing only simple antibiotic therapy with a gravity drip must remain hospitalized. Lastly, the OTA stated, "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 its response to the OTA report, HCFA did not take issue with the observation on varying coverage of infusion services. Also, we were able to verify this variation in coverage through an analysis of payments made by all carriers in 1991 for infusion drugs including antibiotics, immunosuppressives and a chemotherapeutic agent. We noted wide differences in the total amounts paid by carriers for some infusion drugs. Frequently these amounts paid were disproportionate to what could have been expected considering the size of populations served by the carriers. One example is six carriers made payments for IV immunosuppressive drugs in 1991 while 43 made no payments at all. Another noticeable variation in payment occurs in two States with multiple carriers. One State with three carriers had two carriers paying for IV

immune globulin, vancomycin, and FUDR while the third did not pay for any of them.

Comments from our sample infusion companies, and from professional organizations and referring agencies combined also bear out OTA's findings. Forty percent of each group of respondents cite uneven and inadequate Medicare coverage of home infusion as a major issue in the industry. Some believe drugs and biologicals are never covered, while others do not know what is covered and under what circumstances. One respondent reflects the view of many when she says, "Carriers only pay for certain drugs with pumps, but they don't pay for all. We never know." Another says, "Medicare does not pay for hydration and antibiotics. Patients must remain in the hospital, so that triples the cost of therapy." Still another respondent who has experience with several carriers remarks that one carrier pays for antibiotics on a case-by-case basis while another pays for no antibiotics at all. Therefore, the sense of these respondents and others is that patients with similar conditions receive different benefits in different parts of the country. Some respondents mention that they would like clearer direction from HCFA concerning coverage of drugs for home infusion.

PHYSICIAN OWNERSHIP AND OTHER FINANCIAL ARRANGEMENTS ARE COMMON

Physician Ownership

Of the 30 infusion companies in our sample, five (17 percent) report having physician owners. The prior OIG inspection, "Financial Arrangements Between Physicians and Health Care Businesses" found physician ownership in 25 percent of independent clinical laboratories (ICL), 27 percent in independent physiological laboratories (IPL) and 8 percent in DME companies. Although the 17 percent ownership of infusion companies is somewhat lower than the percent for ICLs and IPLs found in the prior OIG study, it is a great deal higher than that for DME companies. This is significant since home infusion is covered under the DME benefit; therefore home infusion companies are a type of DME company.

Among the five company respondents who report having physician owners, four provide all types of home infusion therapies, with the fifth offering only nutrition. All five companies serve patients in a variety of settings and range in size from one to seven locations.

These five ownership arrangements differ and can be characterized as follows:

- One physician owns ten percent of one company's stock, serves as its medical director and is very active in its day-to-day management.

- A physician group clinic with more than 100 physicians owns 15 percent of the second company; none of the physicians, however, allegedly have any major company responsibilities.

- Six physicians own 90 percent of the third company and are responsible for its day-to-day management and all financial matters. They also serve on all company committees.

- Five oncologists at a cancer center own 100 percent of the fourth company. They claim to provide the supplies and pharmaceuticals to just their own patients.

- The fifth company has two physicians who each own one-third of the company's stock and act as its medical directors. The company respondent claims that these physician owners make no referrals to their own company.

In the subsample of 28 physicians, two claim to have less than one percent ownership interest in an infusion company. One of these firms is a publicly traded company. The remaining 26 do not report any ownership.

Many infusion company respondents report a recent "sentinel effect," which has reportedly caused physician financial arrangements to plateau or to virtually disappear. This change reportedly resulted from awareness of investigative activities in the home infusion area.

Nature of Other Financial Arrangements

Ten (33 percent) of the sample infusion companies report having some other sort of financial or business arrangement with one or more physicians. This is more than double the 17 percent compensation arrangement figure found for ICLs, IPLs, and DMEs in the earlier OIG study.

Seven of the ten companies employ physicians as medical directors or as advisory board members in order to acquire JCAHO approval. Respondents say that these physicians typically review the company's policies and procedures, do quality assurance and utilization review, review protocols, write articles and generally advise the company. They are usually paid an annual salary or a flat amount, such as $200 per meeting plus $400 per year.

The remaining three company respondents report having other kinds of financial arrangements. Two have financial arrangements with physicians to provide quality assurance and compliance and the ongoing clinical management of patients. Of these two, one pays the physicians on a case by case basis. The third company has consulting agreements with physicians to review the program's efficiency. The physicians are paid a flat fee on a monthly basis.

A review of the contracts submitted by some of these companies appears to support their statements about the types of arrangements they have. The contracts detail the physicians' responsibilities and payments. Some contracts address Medicare involvement. One contract contains the clause, "Due to Medicare/Medicaid

restrictions, (physician) fees will not be paid under this Agreement on patients eligible for coverage by Medicare or Medicaid, regardless of whether the particular therapy being provided is a Medicare or Medicaid covered service." Another contract talks about safe harbors, "The parties acknowledge that this Agreement and the business relationship created satisfies the requirements of 'safe harbor' provisions for personal services and management contracts set forth in 42 CFR Section 1001.952(d)."

All 10 respondents say they do not bill the Medicare carrier for physician services although they do feel that physicians should be reimbursed for their ongoing management of the patient. Some respondents report that private insurers will, in fact, reimburse physicians for these monitoring services.

While none of the physician respondents report any financial arrangements with infusion companies, six mention financial incentives they had been offered. These include a supervision fee, $100 a patient for referrals or some other fee for referrals, a consulting fee, billing services, and an administration fee for each dialysis patient that gets intradialytic parenteral nutrition. All physicians claimed to have turned down these offers.

The majority of physician respondents report having no input concerning the infusion company used by their patients. Most say this decision is made by the hospital, nursing home, or home health agency with which the patient is associated. Those physicians who do make or influence the decision report hearing about infusion companies from sales people or choosing a company from prior positive experience.

In regard to both the physician ownership and other financial arrangements discussed in this report, we did not have sufficient data to determine the effects that OBRA 1993 would have on Medicare payment for services ordered by physicians with the financial arrangements we found.

Conflicting Perceptions of Financial Arrangements

Perceptions of company, physician and other respondents as to the extent of physician arrangements differ from physicians' and companies' reported behavior, suggesting that the full nature and extent of such arrangements are unclear.

Although 17 percent of infusion company respondents report having physician owners, a majority (53 percent) nevertheless believe physician ownership is either very or somewhat common. In contrast, most physician respondents (64 percent) say either that physician ownership is not at all common or that they do not know how common it is.

The perceptions of infusion company respondents and physician respondents also differ regarding other financial arrangements. Two-thirds of the company respondents believe such arrangements are very or somewhat common, though only one-third report having them. However, only four of the 28 physician respondents feel other

financial arrangements are common, 10 feel they are not common, and 14 do not know.

Most of the 17 representatives of professional organizations and referring agencies believe that physician arrangements are very or somewhat common in the industry. About three-fourths say they know or have heard of specific cases of physician arrangements. Seven of the 17 report knowing of cases where physicians received fees for referrals.

Two-thirds of all respondent types agree that if physician ownership or other financial arrangements does occur, it could lead to kickbacks and possibly, over-referral.

Most respondent types, nevertheless, cite advantages to both physician ownership and other financial arrangements. The major advantage mentioned is profit for the physician, which is seen as having little if any benefit for the patient. Other advantages cited include enhanced quality of care, availability of physician input and expertise, and better integration of care. However, disadvantages are offered more frequently than advantages. These disadvantages include a conflict of interest for the physician which might affect his or her judgement, reduced quality of care, high costs, and the patient's lack of free choice.

Company Characteristics

In attempting to learn about physician financial arrangements with the 57 sample home infusion companies we found that most of the companies in our sample were small in size. This is in contrast to the industry at large which is dominated by a few very large companies. All but one of the top ten infusion companies have at least 70 locations or more nationwide.

Only one of these very large firms shows up in a list of the top ten of our 57 sample companies in terms of their market shares of Medicare patients served in the home. Its nine percent share of Medicare patients is not even the largest. The firm with the highest (13) percent of patients actually cares for a total of only 500 patients at a time, approximately 375 of which are on Medicare, and has but one location. Its patient load is much smaller than that of industry leaders which have several thousand patients each. Also, nine of the top ten Medicare companies in our sample have ten or fewer locations. And none of these nine sample companies shows up on an industry list of the 75 top infusion companies, based on sales and other criteria. Of the ten leading sample companies serving Medicare patients in the home, the top four provide nutrition and other therapies while the next six provide only nutrition.

RECOMMENDATIONS

In light of our findings, we believe that HCFA should:

1) Monitor spending to better track trends. One way this can be accomplished is to identify a unique series of codes for home infusion therapy similar to the approach used in this study.

2) Provide more specific coverage guidelines and

3) Collect ownership and compensation information on form HCFA - 192, use this information to monitor referral and utilization patterns, and refer suspected cases of abuse to the OIG.

COMMENTS

Written comments received from HCFA and verbal comments received from OTA concur with the recommendations of this report. The OTA is concerned that the costs of infusion therapy are underreported in this report because we did not include Medicare Part A services related to pump use. We agree that including Part A services would increase total costs. However, Part A data was not within the focus of this study. Suggestions for changes in the wording, clarifications of the text and any technical changes have for the most part been incorporated into the final report. The actual comments received from HCFA are in Appendix D.

APPENDIX A

METHODOLOGY TO ESTIMATE MEDICARE REIMBURSEMENT

To obtain Medicare reimbursement amounts the same method was used to gather 1990 data and 1991 data. Beneficiaries were identified as infusion patients from the OIG Part B CWF one percent sample when an infusion pump (HCPCS B9000-B9006, E0781, E0791) was found in their Part B services. The place of service code for the pump identified beneficiaries receiving infusion services at home. Infusion services were defined for these beneficiaries as:

B0000 through B8999	Enteral and parenteral therapy
B9000 through B9006, E0791	Enteral and parenteral pumps
E0781	Ambulatory infusion pump
E0776	IV pole
A4214	Sterile saline or water
J7050 through J7130	Various infused medications
J7501	Azathioprine, parenteral
J7503	Cyclosporine, parenteral
J7504	Lymphocyte immune globulin
J7505	Monoclonal antibodies
J9000 through J9999	Chemotherapy
J7190 through J7197	Anti-hemophiliac factor
J2270	Morphine
J0990	Demerol
J2175	Meperidine*

* Listed in HCFA's September 1993 DMERC Supplier Manual as one of a list of drugs used with infusion pumps

APPENDIX B

SAMPLING METHODOLOGY

First, all beneficiaries who had received an infusion pump (HCPCS codes B9000-B9006 or E0781, E0791) were extracted from the 1% 1991 Part B Common Working File (CWF). There were 1,178 of these beneficiaries with 5,210 pumps for a total allowed charge of $594,392.00. Second, the beneficiaries were matched by HICN back to the CWF to get all of their services in 1991 (131,343 line items). These beneficiaries were matched against HCFA's Enrollment Data Base (EDB) to get their State of residence. These steps resulted in information about each of the 1,178 beneficiaries. To obtain a workable sample, each State was given a weight in proportion to the number of pump beneficiaries living in that State. Random numbers were used to pick the 8 states (KS, NY, CA, IL, CT, TX, TN, FL). Next, a simple, random sample was performed to pick a maximum of 30 beneficiaries per State resulting in a total of 200 beneficiaries in the sample (CT and KS combined only have 20).

Table I below shows the number of pump beneficiaries in the sample States and their probability of selection.

TABLE I

NUMBER OF BENEFICIARIES WITH PUMPS IN SAMPLE STATES AND ODDS OF STATES BEING CHOSEN

	No. of Benes	Percent of Total	No. of Chances	Probability of Selection
CALIFORNIA	125	10.61 percent	107	10.22 percent
TEXAS	97	8.23	83	7.93
NEW YORK	66	5.60	57	5.44
FLORIDA	80	6.79	69	6.59
ILLINOIS	49	4.16	43	4.11
TENNESSEE	43	3.65	38	3.63
CONNECTICUT	12	1.02	11	1.05
KANSAS	8	.68	8	.76
SUBTOTAL	480	40.74	416	
U.S. TOTAL	1178		1047	

APPENDIX C

OTA COVERAGE DATA *
Collected February, 1991

HCFA-Sanctioned Coverage for Drugs Under the DME Benefit

Drug	Policy in Medicare Carriers Manual if drug is delivered through an external infusion pump
Morphine:	Covered for intractable cancer pain
Cancer chemotherapy:	Covered for liver cancer and some colorectal cancer patients
Deferoxamine:	Covered for acute iron poisoning or iron overload
Heparin:	Covered in institutional settings to treat thromboembolic disease and pulmonary embolism

Variation in Carrier Coverage Policies for Drugs Under the DME Benefit
Results of an OTA Telephone Survey **

DRUG	NUMBER (PERCENT) OF 43 CARRIERS
MORPHINE	
Cover only for HCFA-specified conditions	29 (67%)
Cover for above and some other conditions	13 (30%)
No claims yet	1 (2%)
CANCER CHEMOTHERAPY	
Cover only for HCFA-specified conditions	17 (40%)
Cover for other cancers/drugs as well	25 (58%)
No claims yet	1 (2%)
DEFEROXAMINE	
Cover only for HCFA-specified conditions	33 (77%)
Cover (rarely) for other indications	3 (7%)
No claims yet	6 (14%)
No response	1 (2%)
HEPARIN	
Responses not reliable - confused home/institutional settings	

DRUG	NUMBER (PERCENT) OF 43 CARRIERS
OTHER ANALGESICS BESIDES MORPHINE	
Cover if patient allergic to morphine or tried unsuccessfully	14 (33%)
Cover with few categorical restrictions	10 (23%)
No claims/do not cover	19 (44%)
ANTIBIOTICS	
Cover for various chronic infections	15 (35%)
Cover only as an adjunct to cancer therapy	2 (5%)
No claims yet (but probably would cover)	1 (2%)
Do not cover	25 (58%)
ADJUNCT CANCER DRUGS (BESIDES CYTOTOXIC DRUGS)	
Cover when prescribed for patients already receiving infused cytotoxic drugs	4 (9%)
Do not cover	39 (91%)
DOBUTAMINE	
Cover for heart transplant candidates	2 (5%)
No claims yet (but would probably cover)	1 (2%)
Do not cover	40 (93%)
HYDRATION	
Cover for patients already receiving other covered infusion therapy	2 (5%)
Do not cover	41 (95%)
AEROSOLIZED PENTAMIDINE ***	
Cover under DME benefit	2 (5%)
Do not cover	41 (95%)

* Not published in final report
** Telephone survey information was not verified in any way
*** Not infused

APPENDIX D

HCFA COMMENTS ON THE DRAFT REPORT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date SEP 3 1993

From Bruce C. Vladeck
Administrator

Subject Office of Inspector General (OIG) Draft Report: "Medicare Home Infusion Therapy" (OEI-02-92-00420)

To Bryan B. Mitchell
Principal Deputy Inspector General

We reviewed the above-referenced draft report which describes the Medicare home infusion industry.

We concur with all of the recommendations contained in the report. Based on our review of trade journals and discussions with infusion industry representatives, we also agree with OIG's findings regarding the rapid increase in expenditures for home infusion therapy. We expect continued growth in the future and support the monitoring of expenditures on home infusion therapy.

Our detailed comments on the report findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please advise us if you agree on our position on the report findings and recommendations at your earliest convenience.

Attachments

Comments of the Health Care Financing Administration (HCFA)
on Office of Inspector General (OIG) Draft Report:
Medicare Home Infusion Therapy
(OEI-02-92-00420)

Recommendation 1

HCFA should monitor spending to better identify trends, perhaps by identifying a unique series of codes for home infusion therapy.

HCFA Response

We concur. Program expenditures for all durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including home infusion therapy equipment, should be monitored closely, especially given the precipitous growth in these expenditures. HCFA has put procedures in place to track trends in infusion therapy. As OIG is aware, HCFA's contract with four durable medical equipment regional carriers (DMERC) will become operational on October 1. One DMERC, in addition to claims processing functions, will serve as a statistical analysis DMERC (SADMERC). The SADMERC will track spending and utilization trends. In order to uniquely identify claims for infusion therapy in the home, HCFA is considering establishing a two-digit modifier to attach to existing codes. Establishing modifiers would prevent the need to create unique codes, which would essentially double the current number of infusion-related codes. Utilizing the analysis of codes, HCFA will be able to track and correct aberrant trends.

Recommendation 2

HCFA should provide more specific coverage guidelines.

HCFA Response

We concur. We are aware that the variability in coverage of home infusion therapy is due to a broad coverage guideline which allows contractors to make independent decisions regarding external infusion pumps. Therefore, we agree that more specific guidance is needed.

In anticipation of the tremendous growth in the home infusion therapy industry, HCFA requested an assessment in September 1986 of the safety and effectiveness of various drug delivery systems, especially infusion pumps, from the Office of Health Technology Assessment (OHTA), Agency for Health Care Policy and Research, Public Health Service. We received OHTA's initial draft report on this issue in late August and are currently reviewing it. We would like to consider OHTA's advice and recommendations before revising national coverage of infusion pumps.

In the interim, the DME regionalization initiative, which involves developing medical review policies for the top 100 items of DME, should bring about a measure of consistency in current coverage. Each DMERC will implement region-wide medical review policy and guidelines. Additionally, the DMERC Medical Directors will continue to meet periodically to review and discuss their regional policies. Efforts will be made to make medical review policies as uniform as possible across regions (though in some cases, uniformity may not be possible because of variations in medical practice from one region to another).

Recommendation 3

HCFA should collect ownership and compensation information on form HCFA-192, use this information to monitor referral and utilization patterns, and refer suspected cases of abuse to OIG.

HCFA Response

We agree. Under the HCFA DMERC initiative, the DMERC servicing the National Supplier Clearinghouse (NSC) will collect information on ownership and management through the use of the supplier registration form (HCFA-192). The ownership data, along with utilization data collected by the SADMERC, will be analyzed by the DMERCs to detect aberrant supplier patterns. The information on aberrant supplier trends will be provided to NSC for flagging suppliers for further review. If a supplier is suspected of abuse, DMERCs will take appropriate action, which may include referral to OIG.

The Omnibus Budget Reconciliation Act of 1993 includes a provision which expands the current ban on physician referrals beyond clinical labs to other services, including DME and parenteral and enteral nutrients, equipment, and supplies. The provision for the expansion in the ban on referrals will be effective after December 31, 1994. Since the DME and parenteral and enteral benefits are the mechanisms by which home infusion therapy is provided under current law, OIG's concerns with respect to ownership and compensation arrangements have been addressed with enactment of this provision.

Technical Comments:

On page 2, line 4 of the second paragraph under "Medicare Coverage of Home Infusion Services," we suggest deleting the words "in order," because they do not appear in the instruction quoted from section 2130 of the Medicare Carriers Manual.

If the data are available, it would be helpful to have the numbers in Table 1 on page 8, Growth of Infusion Services Under Medicare Part B, broken into categories by parenteral, enteral, and other.

It is unclear in a number of instances throughout the report whether OIG is using fiscal or calendar year data. For example, it would be helpful to indicate fiscal or calendar year in the text and chart under the findings listed on page 8.

After reviewing the first draft of the report, it was recommended that some of the HCPCS codes chosen to estimate Medicare reimbursement amounts (Appendix A) not be included. Specifically, OIG included codes J2175 (Meperidine) and J2180 (Meperidine and promethazine HCL). While it is possible to give these analgesics intravenously, it is more likely that they are being given intramuscularly in the home. The revised report still has these codes included. This may lead to an overestimate of home intravenous therapy.

Appendix B gives the percent of total beneficiaries in eight States. The percent for the subtotal should be 40.75, not 40.13. Appendix B is still not clear. It would be helpful to clarify how the Number of Chances column in table 1 was generated.

Appendix C (page C - 2) lists Aerosolized Pentamidine (J2545) as a drug that was included in an OHTA telephone survey. Pentamidine, a drug given to AIDS patients, can be given intravenously, but the aerosolized route is not intravenous.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE HOME INFUSION THERAPY

SEPTEMBER 1993

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program and management problems and recommends courses to correct them.

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The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

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This report was prepared in the New York Regional Office under the direction of Regional Inspector General Thomas F. Tully and Deputy Regional Inspector General Alan S. Meyer. Project Staff included:

New York

Renee Dunn (Project Leader)
Demetra Arapakos
Nancy Harrison

Headquarters

Cathaleen (Kitty) Ahern
W. Mark Krushat
Linda Moscoe

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date APR 22 1993

From William Toby, Jr.
Acting Administrator

Subject Office of Inspector General (OIG) Draft Report: Inappropriate Payments for Total Parenteral Nutrition (TPN) (OEI-12-92-00460)

To Bryan B. Mitchell
Principal Deputy Inspector General

We reviewed the above-referenced draft report which examined Medicare coverage of total parenteral nutrition (TPN), a "high tech" means of feeding patients who do not have a functioning intestinal tract.

Our detailed comments on the report findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please advise us if you agree with our position at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General (OIG) Draft Report:
Inappropriate Payments for Total Parenteral Nutrition (TPN)
(OEI-12-92-00460)

Recommendation 1

HCFA should instruct carriers to adhere to a strict interpretation of the coverage guidelines for TPN.

HCFA Response

We concur. We will issue a notice to remind the parenteral and enteral nutrition specialty carriers of the existing coverage guidelines (contained in sections 2130, 3329, and 4450 of the Medicare Carriers Manual) concerning this use of nutrition. We are particularly concerned about inappropriate coverage of intra-dialytic parenteral nutrition (IDPN), and will draw attention to section 3329.5 of the Medicare Carriers Manual, which addresses renal dialysis patients, in communication with the carriers.

Recommendation 2

HCFA should require the carriers to intensify review of certificates of medical necessity, discuss therapeutic options with physicians, and monitor the use of nutrients over time.

HCFA Response

We concur with the intent of the recommendation. We plan to share copies of the final report with the Durable Medical Equipment Regional Carriers (DMERCs) to make them aware of the potential problem areas identified.

The regionalization of the DMERCs is in the early phases of implementation. During the process of developing region-wide medical policies and screens, the DMERC Medical Directors will re-examine the clinical indications for TPN and examine the appropriateness of providing parenteral nutrition to end-stage renal disease (ESRD) patients. The DMERCs will also be providing the Statistical Analysis Durable Medical Equipment Regional Carrier with claims history data, which will include certificates of medical necessity from which statistically valid samples can be drawn to conduct comprehensive reviews. This will provide more representative samples to serve as the bases for examining trends and patterns of inappropriate TPN payments.

There are Medicaid coverage implications to TPN as well. Section 1902(a)(33) of the Social Security Act requires the State to establish a plan for the review, by an appropriate health professional, of the appropriateness and quality of care and services furnished to recipients of medical assistance. States are required to have procedures in place to review claims submitted by providers. Problems detected during these reviews are brought to the attention of the provider. We believe it would be valuable to alert State Medicaid Agency directors to the TPN coverage issues discussed in this report so that they can consider strengthening Medicaid safeguards as needed. When the report is issued in final, we recommend that OIG send a copy to each State Medicaid Agency director for this purpose.

Recommendation 3

HCFA should review research concerning the use of intra-dialytic parenteral nutrition (IDPN) (parenteral nutrition given to a patient who is being dialyzed).

HCFA Response

We concur with the recommendation. HCFA has asked the Agency for Health Care Policy and Research's Office of Health Technology Assessment (OHTA), PHS, to do a technical review of IDPN for patients with a partially functioning alimentary system. This includes a literature review, as well as contacting the American Society for Parenteral Nutrition for its advice. We will be happy to share the results of this review with OIG when they become available.

Recommendation 4

If IDPN is considered reasonable and necessary for the treatment of a subset of ESRD patients, it should be paid for on a per capita basis, with discounts negotiated by each facility or the networks, or by using some other method that takes into account the efficiencies associated with facility administration of the nutrients.

HCFA Response

We defer comment on this recommendation until the assessment by OHTA of IDPN is completed. Consideration will be given to the OIG's recommendation at that time.

General/Technical Comments:

While OIG randomly sampled the standard 1 percent of the paid claims for parenteral services for 1991, this sample amounted to only 58 claims. It is difficult to assess whether the sample size was adequate for projecting an overpayment of $71 million. It would be helpful to indicate in the methodology section the confidence level achieved and the precision of the projection at that confidence level.

While the review of claims data and the certificates of need often provide excellent information for certain purposes, a medical record review would enhance the value of the report's analysis and findings.

On page 4, it is noted that all hyperalimenation (high- and low-tech feeding methods) claims are processed by one of two carriers: Transamerica Occidental Life Insurance Company in Los Angeles processes claims West of the Mississippi, and Blue Cross/Blue Shield of South Carolina processes claims in the East. The first table in appendix B, however, indicates that South Carolina Blue Shield handled 83 percent of the patients included in the sample. In order to avoid the impression that there is a problem with the sample, it would be helpful on page 4 to indicate that the vast majority of claims are processed by South Carolina Blue Shield.