

June 2010

# HOME INFUSION THERAPY

## Differences between Medicare and Private Insurers' Coverage

**This Report Is Temporarily Restricted Pending  
Official Public Release.**





Highlights of [GAO-10-426](#), a report to congressional requesters

## Why GAO Did This Study

Infusion therapy—drug treatment generally administered intravenously—was once provided strictly in hospitals. However, clinical developments and emphasis on cost containment have prompted a shift to other settings, including the home. Home infusion requires coordination among providers of drugs, equipment, and skilled nursing care, as needed. GAO was asked to review home infusion coverage policies and practices to help inform Medicare policy. In this report, GAO describes (1) coverage of home infusion therapy components under Medicare fee-for-service (FFS), (2) coverage and payment for home infusion therapy by other health insurers—both commercial plans and Medicare Advantage (MA) plans, which provide a private alternative to Medicare FFS, and (3) the utilization and quality management practices that health insurers use with home infusion therapy benefits.

To do this work, GAO reviewed Medicare program statutes, regulations, policies, and benefits data. GAO also interviewed officials of five large private health insurers that offered commercial and MA plans.

## What GAO Recommends

GAO recommends that the Secretary of Health and Human Services conduct a study of home infusion therapy to inform Congress regarding the potential program costs, savings, and other issues associated with a comprehensive Medicare benefit.

[View GAO-10-426](#) or [key components](#). For more information, contact Kathleen M. King at (202) 512-7114 or [kingk@gao.gov](mailto:kingk@gao.gov).

# HOME INFUSION THERAPY

## Differences between Medicare and Private Insurers' Coverage

### What GAO Found

The extent of Medicare FFS coverage of home infusion therapy depends on whether the beneficiary is homebound, as well as other factors related to the beneficiary's condition and treatment needs. Some Medicare FFS beneficiaries who are homebound have comprehensive coverage of home infusion therapy, which includes drugs, equipment and supplies, and skilled nursing services when needed. For non-homebound beneficiaries with particular conditions needing certain drugs and equipment, Medicare FFS coverage of home infusion is limited to the necessary drugs, equipment, and supplies, and excludes nursing services. For other non-homebound beneficiaries, Medicare FFS coverage is further limited; infusion drugs may be covered for those enrolled in a prescription drug plan, but neither equipment and supplies nor nursing services are covered. These non-homebound beneficiaries would need to obtain infusion therapy in a hospital, nursing home, or physician's office to have all therapy components covered.

The health insurers in GAO's study provide comprehensive coverage of home infusion therapy under all of their commercial plans. Some insurers also provide comprehensive coverage under their network-based MA plans, which may provide benefits beyond those required under Medicare FFS. Nationwide, nearly one out of every five MA beneficiaries has comprehensive coverage through an MA plan that has chosen to cover home infusion therapy as a supplemental benefit. To pay providers of home infusion therapy, most of the insurers in GAO's study use a combination of payment mechanisms. These include a fee schedule for infusion drugs, a fee schedule for nursing services, and a bundled payment per day of therapy for all other services and supplies.

Most of the health insurers in GAO's study use standard industry practices to manage utilization of home infusion therapy and ensure quality of care. Specifically, most health insurers require that infusion providers submit patient information in advance to support a request for coverage and receive payment authorization. Also, health insurers may review samples of claims postpayment to determine if claims were billed and paid appropriately. None of the insurers in GAO's study stated that they have had significant problems with improper payments or quality for home infusion therapy services. In addition, health insurers reported taking various steps to ensure the quality of services delivered in the home. These included developing a limited provider network of infusion pharmacies and home health agencies, requiring provider accreditation, coordinating care among providers, and monitoring patient complaints.

In commenting on a draft of this report, the Department of Health and Human Services stated Medicare covers infusion therapy at home for beneficiaries receiving the home health benefit, while other beneficiaries have access to infusion therapy in alternate settings. The Department suggested GAO reword its recommendation to clarify that a change to Medicare benefits would require statutory authority, and GAO has done so.

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## Abbreviations

ASP	average sales price
AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
DME	durable medical equipment
FFS	fee-for-service
HHS	Department of Health and Human Services
MA	Medicare Advantage
OTA	Office of Technology Assessment
TPN	total parenteral nutrition
WAC	wholesale acquisition cost

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United States Government Accountability Office  
Washington, DC 20548

June 7, 2010

The Honorable Frank Pallone, Jr.  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
House of Representatives

The Honorable Eliot L. Engel  
House of Representatives

Infusion therapy—drug treatment generally administered intravenously—was once provided strictly to patients in hospitals. However, clinical developments and a greater emphasis on cost containment over the last 30 years have prompted a shift to providing this therapy in alternate settings, including the home. Home infusion therapy has since become a large industry with estimated net revenues of up to \$11 billion annually, and between 700 and 1,000 home infusion providers, ranging from small local companies to large national ones. Industry experts project the home infusion market will continue to grow steadily, with one expert predicting growth to about \$16 billion by 2012.

Physicians may prescribe infusion therapy when they determine that oral medications may not be effective. During infusion therapy, drugs are generally administered into a vein using a device to control the rate of drug flow. Such devices include gravity drip systems, which rely on gravity to move the drug into the patient, and electronic infusion pumps that may be programmed to deliver constant and precise amounts of the drug. Commonly infused drugs include antibiotics that may be administered multiple times each day over several weeks to treat infections and analgesics that may be infused continuously over months or years to relieve pain. In addition to the specialized equipment and prescribed drugs, home infusion therapy requires other components, such as skilled nursing care and supplies. The complex nature of home infusion therapy also requires coordination of care among providers of these components.

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Currently, Medicare—the federal health insurance program for people aged 65 and older and certain other individuals<sup>1</sup>—does not have a distinct benefit for home infusion therapy that provides coverage for all components for all beneficiaries. Efforts to extend coverage to this treatment setting date back to the 1980s,<sup>2</sup> and recently, some members of Congress have expressed renewed interest in establishing a home infusion therapy benefit.<sup>3</sup> The proposed benefit would provide coverage of all components of home infusion therapy for all Medicare beneficiaries enrolled in the traditional fee-for-service (FFS) program as well as those in the Medicare Advantage (MA) program<sup>4</sup>—in which beneficiaries enroll in health plans offered by private entities that contract with the Centers for Medicare & Medicaid Services (CMS).<sup>5</sup>

You asked us to review home infusion therapy coverage policies and practices to inform the development of Medicare policy. Specifically, you asked us to develop information on Medicare FFS and private health insurers—both commercial health plans and MA plans, which, in addition to providing the benefits covered by Medicare FFS,<sup>6</sup> may cover more services. In this report, we describe (1) coverage of home infusion therapy components under Medicare FFS, (2) coverage and payment for home infusion therapy under other health insurers—both commercial and MA plans, and (3) the utilization and quality management practices, if any, that health insurers use with home infusion therapy benefits.

To describe the extent to which Medicare FFS covers the components of home infusion therapy, we reviewed federal statutes, regulations, and policies issued by CMS. We also reviewed national and local coverage

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<sup>1</sup>Medicare also covers certain individuals with disabilities and individuals with end-stage renal disease. In 2008, Medicare covered about 45 million beneficiaries, nearly 8 million of whom were dually eligible for both Medicare and supplemental coverage under their state Medicaid programs.

<sup>2</sup>See Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 203, 102 Stat. 683.

<sup>3</sup>H.R. 574, 111th Cong. (2009), and S. 254, 111th Cong. (2009).

<sup>4</sup>Traditionally, Medicare FFS included Medicare Part A (hospital insurance) and Part B (supplementary medical insurance). For purposes of this report, we are also including Part D (outpatient prescription drug coverage) in our analysis of Medicare FFS.

<sup>5</sup>CMS is the agency within the Department of Health and Human Services that administers the Medicare program.

<sup>6</sup>An exception is hospice care, a benefit provided under Medicare FFS but not covered in the MA program.

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determinations—policies specifying items and services covered by Medicare. We also talked to CMS officials responsible for various Medicare program components.

To determine coverage and payment for home infusion therapy under other health insurers, we interviewed officials from a selective sample of health insurers. We contacted officials of MA plans and commercial plans sponsored by six of the largest MA organizations and one additional commercial health plan. Five of the six MA organizations responded within our chosen time frame and were included in our study. This selective sample of MA organizations enrolled about 45 percent of all MA beneficiaries as of June 2009. The information we obtained is not generalizable to all health insurers. In addition, we examined the plan benefit packages that MA organizations submitted to CMS for contract years 2009 and 2010. To obtain an industry perspective, we interviewed representatives of the National Home Infusion Association and Infectious Diseases Society of America as well as one home infusion provider.

To identify utilization and quality management practices that health insurers may use with home infusion therapy benefits, we discussed these issues with officials of our sample plans. In addition, we interviewed an official from a large utilization management organization who has expertise regarding the home infusion industry. We also interviewed officials and reviewed materials from organizations that accredit home infusion providers—the Accreditation Commission for Health Care, the Community Health Accreditation Program, and the Joint Commission—regarding potential quality and safety concerns related to these providers.

We conducted this performance audit from February 2009 through May 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

Patients receive infusion therapy for a variety of conditions, and physicians may determine that the home is an appropriate venue for treatment based on a particular patient's condition and circumstances. Medicare covers and pays for a range of health care services, equipment, and drugs, and uses various payment systems. Over the last three decades, Congress has taken steps to address coverage of home infusion therapy.

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## Home Infusion Therapy Patients and Providers

Patients may receive home infusion therapy for acute conditions, such as infections unresponsive to oral antibiotics<sup>7</sup> or pain management (cancer-related or postsurgical), or for chronic conditions such as multiple sclerosis or rheumatoid arthritis. Prior to initiating infusion therapy in the home, physicians and home infusion providers first assess the appropriateness of home treatment for the needed drug therapy and for the patient's condition. They then determine whether the patient is able to understand and carry out therapy procedures, and if the patient has family or other caregivers available to provide assistance. For certain therapies, such as antibiotic therapy, the patient or a family member may be taught to administer the drug. In these cases, a nurse would generally visit once or twice at the beginning of treatment, and then once per week throughout the course of treatment. Other therapies may require more frequent nursing care. The home setting is not appropriate for all patients receiving infusion therapy, for all conditions, or for all drugs.

Many patients receive home infusion therapy following a hospital stay. The home infusion provider may provide any necessary skilled nursing services directly or may contract with a home health agency to do so. Some patients receive home infusion therapy for chronic conditions that may not require hospitalization; in these cases, a patient's physician may order the therapy to be delivered by a home infusion provider after diagnosis. Outside of the home, patients may also receive infusion therapy in an independent infusion center, a physician's office, or a hospital-based infusion clinic.

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## Medicare Payment Systems and Methods

Since it was established in 1965, the structure of Medicare and the benefits covered by the program have evolved. Currently, Medicare consists of four parts, A through D:

- **Medicare Part A:** Covers inpatient hospital stays, as well as skilled nursing facility care, hospice care, and home health care.<sup>8</sup> To be eligible for covered home health services—which include skilled nursing care,

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<sup>7</sup>Commonly infused antibiotics include ceftriaxone, vancomycin, daptomycin, ertapenem, cefepime, cefazolin, piperacillin/tazobactam, and meropenem, according to industry experts.

<sup>8</sup>Home health care is covered under Part A for beneficiaries needing treatment following a stay in the hospital and for those not enrolled in Part B. Home health care is covered under Part B for beneficiaries who have not been recently discharged from the hospital and, in some cases, when beneficiaries have exhausted their coverage under Part A.



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physical therapy, and occupational therapy—a beneficiary must be homebound and have a home health plan of care approved by his or her physician.<sup>9</sup> In 2008, approximately 3.2 million, or about 7 percent of all Medicare beneficiaries, received home health services. Medicare pays home health agencies that provide these services using a prospective payment system under which they receive a predetermined rate for each 60-day episode of home health care. The payment amounts are generally based on patient condition and service use.

- **Medicare Part B:** Provides optional coverage for hospital outpatient, physician, and other services, such as laboratory services. It also covers durable medical equipment (DME) and supplies,<sup>10</sup> including infusion pumps and other equipment needed for infusion therapy.<sup>11</sup> Medicare pays for many Part B services and supplies using fee schedules, and beneficiaries enrolled in Part B are generally responsible for paying monthly premiums as well as coinsurance for services they receive.<sup>12</sup> Certain specified outpatient prescription drugs also are covered under Part B, including drugs needed for the effective use of DME. Part B drugs are generally paid based on a fee schedule; infusion drugs covered under the DME benefit are paid based on a different fee schedule than other Part B drugs.
- **Medicare Part C:** Since the 1970s, most Medicare beneficiaries have had the option to receive their Medicare benefits through private health insurance plans—now known as MA plans—under Medicare Part C. In 2008, nearly one out of every four Medicare beneficiaries was enrolled in an MA plan. MA organizations enter into contracts with CMS that require

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<sup>9</sup>Medicare designates beneficiaries as homebound if they are able to leave home only with great difficulty and for absences that are infrequent and of short duration or for the purpose of receiving medical care. In this report, our use of the term “homebound” refers to this Medicare definition.

<sup>10</sup>DME is reusable medical equipment such as wheelchairs or hospital beds. See 42 C.F.R. § 414.202 (2010). Medicare-reimbursed supplies include items that are used and consumed with DME, such as drugs used for inhalation therapy, or that need to be replaced frequently (usually daily), such as surgical dressings.

<sup>11</sup>An infusion pump may be necessary for patients receiving therapies of extremely high or low dosage, therapies of long duration or frequent administration, or therapies needing a carefully controlled rate of administration. Other infusion devices, such as intravenous gravity drip systems, are considered to be appropriate in many other cases.

<sup>12</sup>Medicare FFS beneficiaries can purchase Medigap insurance policies, offered by private insurers, that help cover cost-sharing amounts for Medicare-covered services.

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plans to cover Medicare Part A and B services.<sup>13</sup> These organizations have flexibility in designing their plan benefit packages and may offer additional benefits. Medicare pays MA plans a fixed amount per beneficiary per month—based in part on the projected expenditures for providing Medicare-covered services—and adjusts payments to account for beneficiary health status.

- **Medicare Part D:** First offered in 2006, Medicare Part D provides optional coverage of outpatient drugs, including infusion drugs, to beneficiaries who enroll in prescription drug plans offered by private entities.<sup>14</sup> Medicare beneficiaries may receive Part D drug coverage through stand-alone prescription drug plans or through MA plans that include drug coverage. Each Part D plan maintains a list of drugs it will cover—a formulary—that must meet certain criteria,<sup>15</sup> and may organize those drugs into pricing groups or tiers.<sup>16</sup> Part D plans contract with pharmacies to create a network of participating providers. Medicare makes subsidy payments to Part D plans, and most beneficiaries pay applicable premiums and cost sharing. Plans negotiate drug prices with drug manufacturers and pharmacies. As such, payment for a drug covered under Part D could be different than payment for the same drug were it covered under Part B. In general, Part D does not cover drugs for which payment is available under Parts A or B.<sup>17</sup>

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<sup>13</sup>MA plans do not cover hospice care, a benefit which is provided under Medicare FFS.

<sup>14</sup>See the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 § 101, 117 Stat. 2066, 2071 (2003) (codified, as amended, at 42 U.S.C. § 1395w-101).

<sup>15</sup>Formularies must include drugs within each therapeutic category and class of covered Part D drugs. CMS generally requires drug plan sponsors to cover at least two Part D drugs in each category and class, subject to approved exceptions or instances when there is only one drug in a particular category or class.

<sup>16</sup>Plan formularies commonly have three tiers, with an additional tier for specialty drugs. On a typical three-tier formulary, tier 1 might consist of low-cost generic drugs, tiers 2 and 3 would comprise brand-name drugs, and an additional tier would include high-cost specialty drugs. Plans do not consistently list the same drugs on the same tiers.

<sup>17</sup>See 42 C.F.R. § 423.100.

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Both home-based services and outpatient infusion therapy have been areas of concern for Medicare program integrity.<sup>18</sup> Recently, the Department of Health and Human Services (HHS) and the Department of Justice have renewed attempts to reduce inappropriate utilization and fraudulent activities in these areas.<sup>19</sup> According to an HHS official, CMS has completed demonstrations that involve strengthening the initial provider and supplier enrollment processes to prevent unscrupulous DME and home health care providers from entering the program. The demonstrations also incorporated criminal background checks of providers, owners, and managing employees into the provider enrollment process. In addition, CMS has found instances of infusion clinics and office-based practitioners billing Medicare for infusion services that were not medically necessary or were not actually provided.

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## Congressional Action and Regulatory History

Despite the lack of a distinct benefit for home infusion therapy, Medicare policies have played a significant role in the development of the home infusion industry. Specifically, Medicare's coverage of certain therapies—enteral and total parenteral nutrition (TPN)<sup>20</sup>—in the home beginning in the late 1970s, and the subsequent implementation of prospective payment for Medicare inpatient hospital services in 1983, contributed to the rapid growth of the home infusion industry during the 1980s.<sup>21</sup>

Over the last three decades, Congress has taken steps to address expanding Medicare coverage of home infusion therapy. The Medicare Catastrophic Coverage Act of 1988 created a home infusion therapy

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<sup>18</sup>We have previously reported on Medicare improper payments for items and services in the home. See GAO, *Medicare: Improvements Needed to Address Improper Payments in Home Health*, [GAO-09-185](#) (Washington, D.C.: Feb. 27, 2009); *Medicare: Covert Testing Exposes Weaknesses in the Durable Medical Equipment Supplier Screening Process*, [GAO-08-955](#) (Washington, D.C.: July 3, 2008); and *Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies*, [GAO-07-59](#) (Washington, D.C.: Jan. 31, 2007).

<sup>19</sup>U.S. Senate, Committee on the Judiciary, *Effective Strategies for Preventing Health Care Fraud*, 111th Cong., 1st sess., October 28, 2009.

<sup>20</sup>TPN is a method of feeding a patient intravenously that is used when the patient's gastrointestinal tract cannot tolerate nutrition by mouth or a feeding tube. Enteral nutrition employs a feeding tube to deliver a liquid nutritional formula to the stomach or small intestine.

<sup>21</sup>The change in payment mechanism for hospitals from per day to per episode created an incentive to reduce the length of stay.

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benefit for all Medicare beneficiaries.<sup>22</sup> The benefit would have provided comprehensive coverage of all the components of home infusion therapy, including intravenous drugs, equipment and supplies, and skilled nursing services when needed. The act called for a per diem fee schedule to pay for the supplies and services used in home infusion therapy and set forth qualifications for infusion providers. Before the provision became effective, however, it was repealed.<sup>23</sup>

At the request of the Senate Committee on Finance, the Office of Technology Assessment (OTA) conducted an extensive study of home infusion therapy, released in 1992.<sup>24</sup> The study examined trends in the industry, the safety and efficacy of the technology, and the implications for Medicare coverage, including various coverage and payment options available at the time. OTA found that additional Medicare coverage of home infusion therapy might lead to lower payments to hospitals in some cases because of shorter stays and lower costs. Yet, OTA concluded that Medicare coverage of home infusion therapy could increase overall Medicare spending.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 expanded coverage of home infusion therapy significantly, in that home infusion therapy drugs were covered for beneficiaries enrolled in Part D plans beginning in 2006.<sup>25</sup> Subsequently, CMS released guidance for Part D plan sponsors on their responsibilities in covering home infusion therapy drugs, which may be more complicated to dispense than oral medications. One element of the guidance stated that Part D plan sponsors should ensure that home infusion drugs are dispensed by network pharmacies in a usable form that can be readily administered in beneficiaries' homes.

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<sup>22</sup>Pub. L. No. 100-360, § 203, 102 Stat. at 721-25.

<sup>23</sup>Pub. L. No. 101-234, § 201(a)(1). The repeal of many provisions of the act was largely attributed to negative public reaction to increased taxes on Medicare beneficiaries, which would have been needed to finance the main goal of the legislation—an overall limit on how much beneficiaries would pay out of pocket for health care.

<sup>24</sup>Office of Technology Assessment, *Home Drug Infusion Therapy Under Medicare*, OTA-H-509 (Washington, D.C., May 1992).

<sup>25</sup>See Pub. L. No. 108-173 § 101, 117 Stat. 2066, 2071-2152.

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In January 2009, members of the House and Senate introduced bills that would create a home infusion therapy benefit that provides comprehensive coverage for all Medicare beneficiaries.<sup>26</sup> The proposed legislation called for coverage of infusion-related services, supplies, and equipment under Medicare Part B. The legislation also called for supplies and equipment to be paid through a set fee per day of service, while nursing services would be paid separately based on a fee schedule. Coverage of the drugs used in home infusions would be consolidated under Medicare Part D. Supporters of the legislation have asserted that providing comprehensive coverage of infusion therapy in the home would generate cost savings for the Medicare program, and that beneficiaries who would prefer having treatments at home could not afford it without Medicare coverage. However, concerns have been raised that additional coverage could add to the Medicare program's growth in spending.

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## Medicare FFS Covers Home Infusion Therapy for Some Homebound Beneficiaries; Coverage Is Limited for All Other Beneficiaries

Medicare FFS covers components of home infusion therapy in some circumstances. The extent of coverage depends on whether the beneficiary is homebound, as well as factors related to the beneficiary's condition and treatment needs. For some homebound beneficiaries, Medicare FFS covers all the components of home infusion therapy, while other homebound beneficiaries have limited coverage. Non-homebound beneficiaries who have certain conditions and who require certain drugs and equipment are covered by Medicare FFS for some components of home infusion therapy. Other non-homebound beneficiaries have little or no coverage for home infusion therapy under Medicare FFS.

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## Some Homebound Beneficiaries Have Comprehensive Coverage of Home Infusion Therapy, and Others Have Limited Coverage

Some Medicare FFS beneficiaries who are homebound—that is, generally confined to their homes and in need of nursing care on an intermittent basis—have coverage for all components of home infusion therapy. (See fig. 1.) Because these beneficiaries qualify for Medicare's home health benefit, the skilled nursing services—such as training, medication administration, and assessment of the patient's condition—as well as certain equipment and supplies used at home are covered. These services, equipment, and supplies are provided by or arranged for by a home health

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<sup>26</sup>H.R. 574, 111th Cong. (2009), and S. 254, 111th Cong. (2009).

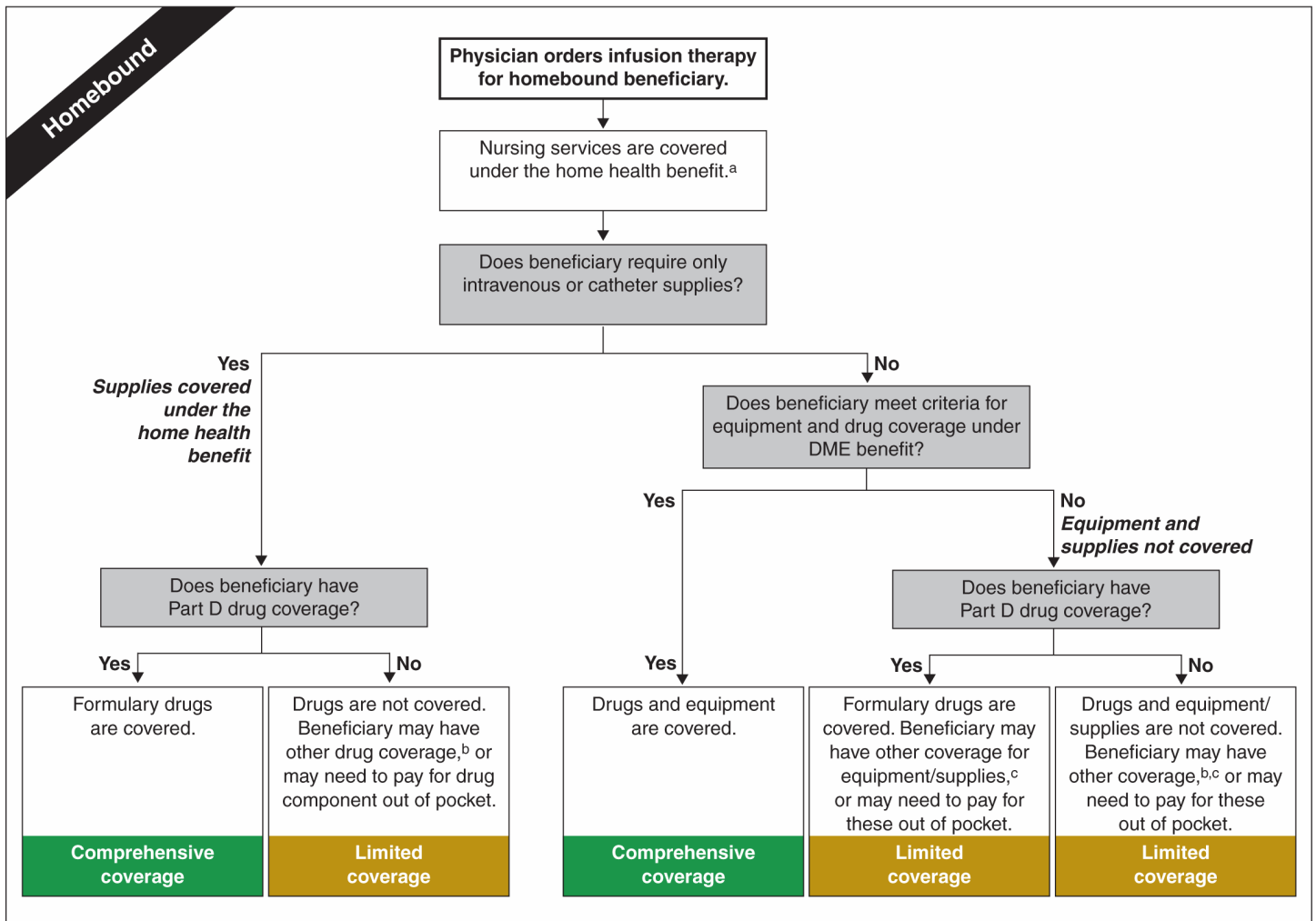
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agency according to a physician's plan of care.<sup>27</sup> Any care coordination or clinical monitoring services needed with home infusion therapy would be provided by the home health nurse assisting the beneficiary at home or by the physician who ordered the therapy. The equipment and supplies covered for homebound beneficiaries include certain infusion pumps covered as DME and supplies such as intravenous and catheter supplies. Homebound beneficiaries who require other equipment, such as disposable infusion pumps, would not have coverage for those items, and therefore have limited coverage.

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<sup>27</sup>If a beneficiary meets all of the criteria for coverage of home health services and the home health agency is providing care under Part A, any DME provided to that patient and billed by the home health agency must also be provided under Part A. In situations in which the patient meets the criteria for coverage of home health services and the home health agency is providing the home health care under Part B because the patient is not eligible for Part A, the DME provided by the home health agency may be furnished under Part B.

**Figure 1: Medicare Fee-for-Service Coverage of Home Infusion Components for Homebound Beneficiaries**



Source: GAO analysis of federal statutes, federal regulations, and CMS guidance.

Note: Medicare designates a beneficiary as homebound if he/she is able to leave home only with great difficulty and for absences that are infrequent and of short duration or for the purpose of seeking medical care.

<sup>a</sup>If a beneficiary meets all of the criteria for coverage of home health services and the home health agency is providing care under Part A, any DME provided to that patient and billed by the home health agency must also be provided under Part A. In situations in which the patient meets the criteria for coverage of home health services and the home health agency is providing the home health care under Part B because the patient is not eligible for Part A, the DME provided by the home health agency may be furnished under Part B.

<sup>b</sup>Beneficiaries may receive additional drug coverage from other sources, such as an employer or retiree plan.

<sup>c</sup>Beneficiaries may receive additional coverage for equipment and supplies from other sources, such as a state Medicaid program.

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Although coverage of drugs is specifically excluded under the home health benefit, coverage for infusion drugs may be obtained through other parts of the Medicare FFS program. For beneficiaries with certain conditions, certain drugs are considered supplies for needed equipment and are therefore covered under the DME benefit. In addition, infusion drugs may be covered for beneficiaries who are enrolled in Part D plans or have other prescription drug coverage. In 2008, approximately 90 percent of all Medicare beneficiaries had prescription drug coverage through Part D plans, retiree plans, or other sources. CMS requires Part D plans to ensure appropriate beneficiary access to commonly infused drugs or drug classes by including them in their formularies and making sure that multiple strengths and dosage forms are available for each covered drug.

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**Non-Homebound  
Beneficiaries with Certain  
Conditions Have Limited  
Coverage of Home  
Infusion Therapy, but  
Others Have Little or No  
Coverage**

For non-homebound beneficiaries with certain conditions, Medicare Part B provides limited coverage of home infusion therapy. Specifically, the DME benefit covers certain equipment and associated drugs for beneficiaries with specified conditions, but does not cover other equipment and drugs or any skilled nursing services.<sup>28</sup> (See fig. 2.) In 2008, about 50,000 Medicare FFS beneficiaries received home infusion therapy under this benefit, according to CMS analysis of claims data for covered infusion pumps.<sup>29</sup> In addition, Medicare Part B expressly provides coverage for other home infusion drugs, such as intravenous immune globulin.

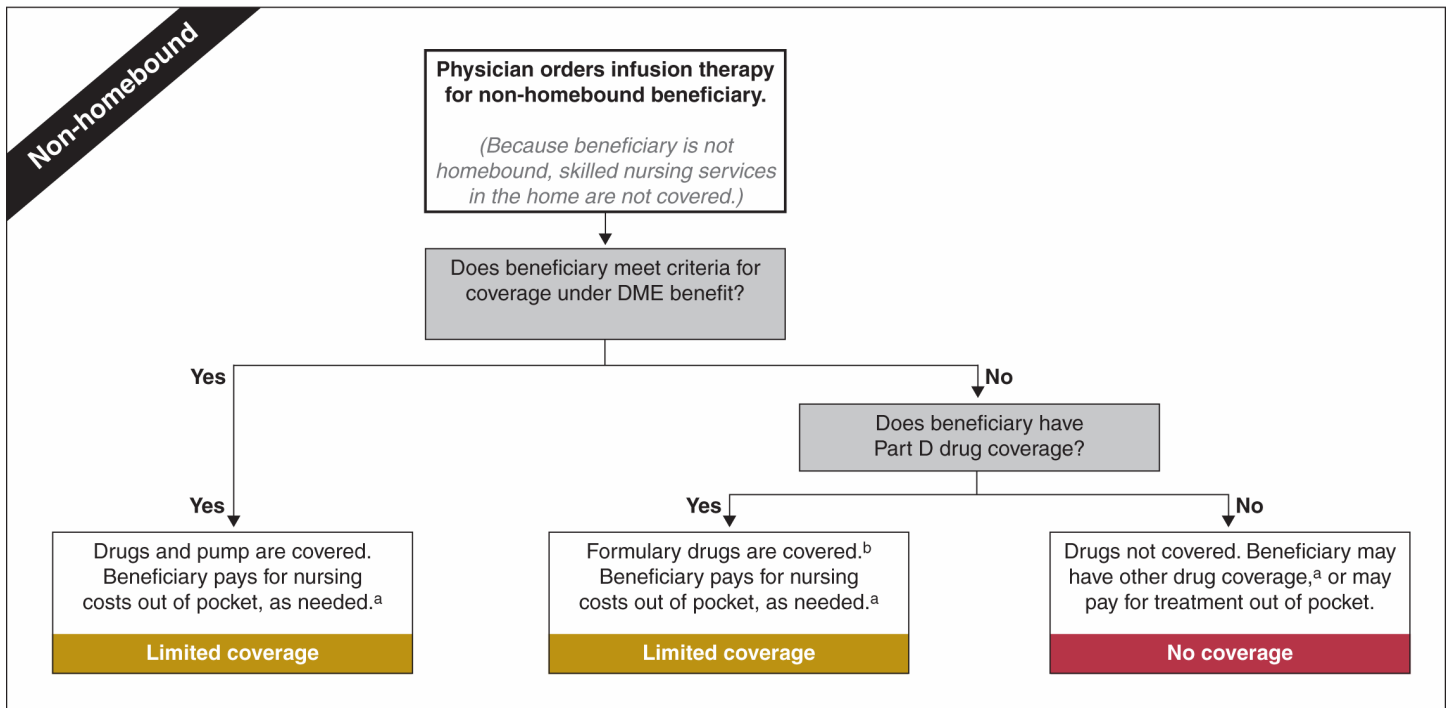
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<sup>28</sup>Medicare FFS does not pay a dispensing fee for Part B drugs, including DME drugs.

<sup>29</sup>These data include infusion pumps provided to homebound as well as non-homebound beneficiaries; the data provided by CMS did not distinguish between the two.



**Figure 2: Medicare Fee-for-Service Coverage of Home Infusion Components for Non-Homebound Beneficiaries**



Source: GAO analysis of federal statutes, federal regulations, and CMS guidance.

<sup>a</sup>Beneficiaries may receive additional coverage for nursing services and drugs from other sources, such as an employer or retiree plan.

<sup>b</sup>Part D plans must require contracted network pharmacies that deliver home infusion drugs to ensure that the other components of therapy are in place before dispensing home infusion drugs.

Under the DME benefit, Medicare covers certain infusion pumps, as well as the infusion drugs that are considered supplies needed for the effective use of the infusion pump, for treatment of particular conditions as specified in national and local coverage policies.<sup>30</sup> Medicare’s national coverage policy related to home infusion details several conditions for which pumps and certain drugs would be covered. The local coverage policies for home infusion outline additional circumstances in which pumps and drugs may be covered, and are required by CMS to be identical. One policy we reviewed listed about 30 specific drugs covered for certain conditions when treated using an external infusion pump. Examples of the

<sup>30</sup>National coverage policies are developed by CMS, and local coverage policies are developed by regional contractors that process DME claims.

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limited circumstances in which infusion pumps and related drugs would be covered under the DME benefit include

- morphine administered by external infusion pump for beneficiaries with intractable pain caused by cancer,
- deferoxamine administered by external infusion pump for the treatment of acute iron poisoning and iron overload, and
- TPN administered by infusion pump for patients with a permanent, severe disease or disorder of the gastrointestinal tract.

At the same time, national and local coverage policies explicitly exclude certain types of infusion pumps or drugs for certain conditions. For example, Medicare does not cover an implantable infusion pump for the treatment of diabetes because, according to CMS, data do not demonstrate that the pump would provide effective administration of insulin. Medicare coverage also excludes external infusion pumps used to administer vancomycin, a commonly infused antibiotic. According to CMS, this method of treatment is specifically excluded from coverage because of insufficient evidence that an external infusion pump—rather than a disposable pump or the gravity drip method—is needed to safely administer vancomycin. In addition, drugs administered through other methods, such as intravenous gravity drip, are not covered under the DME benefit.

Non-homebound beneficiaries needing therapies not covered under Medicare Part B may have coverage of infusion drugs under Part D, but they lack coverage for the other components of home infusion therapy—skilled nursing services, equipment, and supplies. (See fig. 2.) Therefore, these non-homebound beneficiaries would need to seek treatment in another setting—such as a hospital, nursing home, or physician’s office—to have all of the components of infusion therapy covered.

Under Part D, drug plans must ensure that certain requirements are met before drugs, including infusion drugs for administration at home, may be dispensed.<sup>31</sup> Specifically, Part D plans must require that their contracted network pharmacies ensure that the other components of therapy are in

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<sup>31</sup>See 42 C.F.R. § 423.153(c).

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place before dispensing home infusion drugs.<sup>32</sup> Pharmacies may, in turn, seek assurances that another entity, such as a home health agency, can arrange for other needed services.

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## Many Health Insurers Cover Home Infusion Therapy and Use a Combination of Payment Methods

The health insurers in our study told us that they provide comprehensive coverage of home infusion therapy under all of their commercial health plans and some MA plans. Most of these insurers use a combination of payment mechanisms that include a fee schedule for infusion drugs, a fee schedule for nursing services, and a bundled payment per day for therapy for all other services and supplies provided.

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## Commercial Health Plans and Some MA Plans Provide Comprehensive Coverage of Home Infusion Therapy

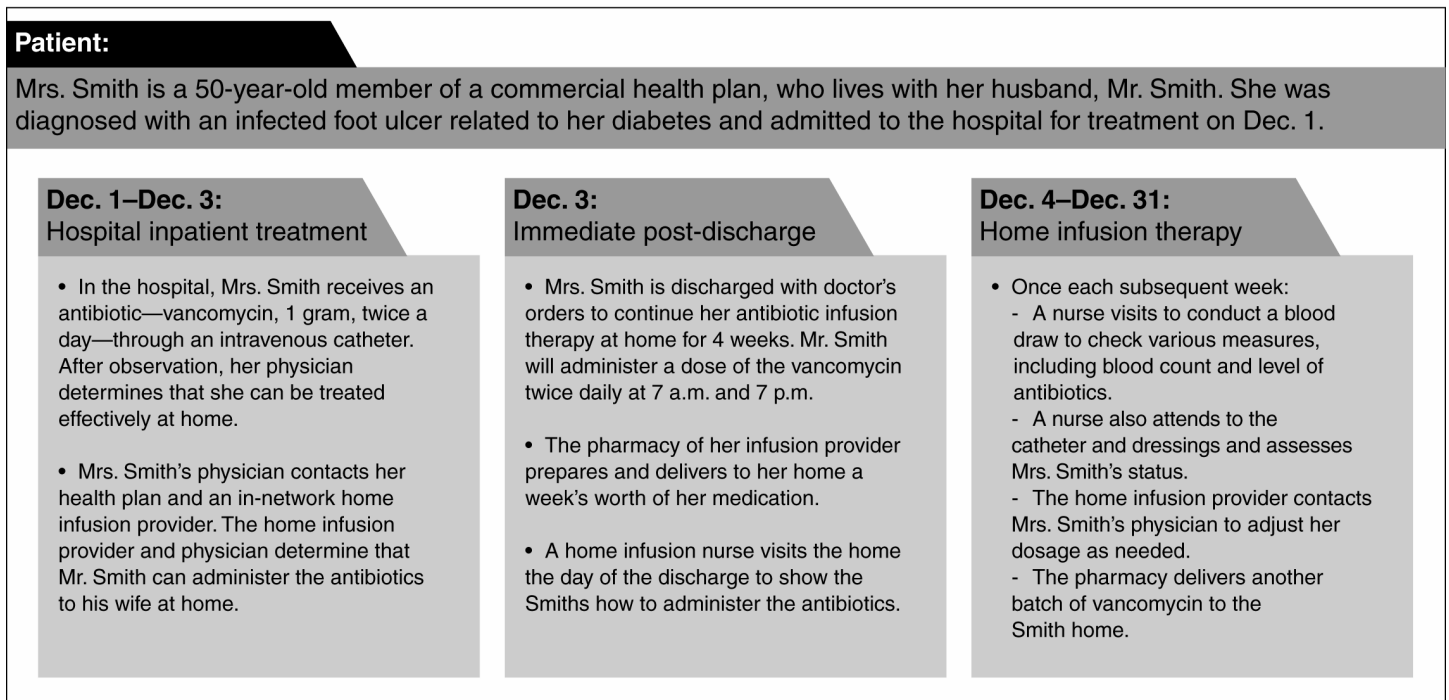
The health insurers in our study told us that they provide comprehensive coverage of home infusion therapy under all of their commercial health plans and some MA plans. Most of them reported that they have covered infusion therapy at home for more than 10 years—one for more than 25 years—and that few or no members experienced problems with access to home infusion services. Spokespeople for these insurers generally anticipated more opportunities for home infusion therapy in the future, as more infusion drugs are developed and technology evolves to infuse them safely in the home.

All of the health insurers told us that home infusion therapy coverage was comprehensive and available to all members under their commercial health plans. (See fig. 3 for a hypothetical example of how home infusion therapy might be covered under a commercial health plan.) They also told us that their commercial coverage policies have few or no limitations or exclusions on home infusion therapy, although coverage may be denied when the drug's label specifies another setting as the appropriate venue, such as a hospital or physician's office.

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<sup>32</sup>According to CMS, while Part D sponsors remain responsible for complying with all Part D requirements, they are permitted to delegate their responsibilities to network pharmacies.

**Figure 3: Hypothetical Example of Home Infusion Therapy Coverage in a Commercial Health Plan**



Source: GAO.

Note: This hypothetical example of home infusion therapy does not address problems patients may have during the course of treatment, such as changes in medication or infections.

Some insurers mentioned that chemotherapy infusions are rarely administered in the home. One insurer stated that infusion drugs for home use must have a low likelihood of adverse reaction, and that few chemotherapy drugs meet that criterion. Even when the home is a safe setting for such therapy, there may be other reasons to infuse chemotherapy drugs in another setting. For example, another insurer pointed out that cancer treatments might require blood tests prior to the infusion, and fewer supplies would be used if the patient had both the blood testing and the infusion in a physician’s office.<sup>33</sup>

<sup>33</sup>In addition to safety and cost concerns, prescribing physicians may have a financial incentive to infuse chemotherapy drugs in their offices rather than ordering infusion services for the home, according to one insurance spokesperson.

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Of the five health insurers that had MA plans, two said they provide comprehensive coverage of home infusion therapy for MA beneficiaries in the same manner as for their commercial plan members.<sup>34</sup> The remaining three insurers told us that their MA plans' policies generally follow Medicare FFS coverage. However, two of these insurers noted that their MA plans may extend coverage to non-homebound beneficiaries on a case-by-case basis. They said that while such MA beneficiaries may be able to leave their homes with little difficulty, it may not be practical for them to go to an outpatient department or infusion clinic three times a day to receive infusion therapy. In those cases, the MA plan might cover infusion therapy administered at beneficiaries' homes.

Nationwide, nearly one out of every five MA beneficiaries has comprehensive coverage of home infusion therapy through a bundle that includes drugs and associated supplies and services. CMS allows MA plans to cover infusion drugs as a Part C mandatory supplemental benefit—a benefit not covered by Medicare FFS, but available to every beneficiary in the plan—to better coordinate benefits for home infusion therapy under Parts C and D.<sup>35</sup> According to CMS, allowing MA plans to cover infusion drugs in this way would also facilitate access to home infusion therapy—including drugs as well as the other needed components—and obviate the need for more costly hospital stays and outpatient services. CMS data show that programwide, roughly 5 percent of MA plans chose to cover infusion drugs as a supplemental benefit: 258 plans representing almost 20 percent of MA beneficiaries in 2009 and 224 plans representing more than 18 percent of MA beneficiaries in 2010. Of the insurers we interviewed, one offers comprehensive coverage in this manner.

Health insurer officials we talked to asserted that infusion therapy at home generally costs less than treatment in other settings. Hospital inpatient care was recognized as the most costly setting. One insurer estimated that infusion therapy in a hospital could cost up to three times as much as the same therapy provided in the home. Another insurer reported that its infusion therapy benefit is structured to encourage beneficiaries to receive

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<sup>34</sup>One of these insurers provides comprehensive coverage of home infusion therapy in all of its MA plans except private fee-for-service plans. Unlike network-based MA plans, such as health maintenance organizations or preferred provider organizations, private fee-for-service plans are not currently required to have networks of contracted providers if they pay providers Medicare FFS rates or higher.

<sup>35</sup>CMS has allowed plans to cover infusion drugs under Part C since 2007.

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services at home rather than in a hospital inpatient or outpatient setting whenever possible. For example, members of that insurer's health plans have no out-of-pocket costs for home infusion therapy.

However, the relative costs of infusion therapy in physicians' offices and infusion clinics compared to the home were less clear. For example, some health insurers stated that the cost of infusion therapy provided in an infusion center may be similar to the cost of treatment at home because nurses at infusion centers can monitor more than one patient at a time. At the same time, other insurers stated that infusion centers incur facility costs, such as rent and building maintenance, which could account for higher costs compared with home infusion.

The home may not be the most cost-effective setting for infusion therapy in all cases, given the variability of patient conditions and treatment needs. An insurer noted, for example, that if a patient needs a onetime infusion rather than a longer term treatment, a physician's office may be the least costly setting. Similarly, another insurer stated that it may not be cost-effective or practical for a patient to be treated at home if that patient requires more than two nursing visits a day—in such a case, treatment in an inpatient setting or nursing home might be more appropriate.

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### Most Health Insurers Use a Combination of Payment Methods for the Components of Home Infusion Therapy

Most of the health insurers we spoke with use a combination of methods to pay providers for the different components of home infusion. (See fig. 4 for an example of how a commercial health plan might pay for a typical home infusion case, as introduced in fig. 3.) For infusion drugs, they commonly use a fee schedule, which they update periodically—as frequently as quarterly. Depending on the particular plan and negotiations with individual infusion providers, insurers told us they develop payment amounts for drugs based on one or more of the following:

- Average wholesale prices (AWP) are list prices developed by manufacturers and reported to organizations that publish them in drug price compendia. There are no requirements or conventions that AWP reflect the price of an actual sale of drugs by a manufacturer.
- Average sales prices (ASP) are averages, calculated quarterly from price and volume data reported by drug manufacturers, of sales to all U.S. purchasers, net of rebates and other price concessions. Certain prices are excluded, including prices paid to federal purchasers and prices for drugs furnished under Part D. Under Medicare FFS, infusion drugs

administered using a covered DME item are generally paid at 95 percent of the October 1, 2003 AWP.<sup>36</sup>

- Wholesale acquisition costs (WAC) are manufacturer list prices to wholesalers or direct purchasers, not including discounts or rebates.

**Figure 4: Hypothetical Example of Home Infusion Therapy Payment in a Commercial Health Plan**

<b>Payment:</b>															
<p>Mrs. Smith's commercial health plan pays weekly claims that list the amount and type of drugs purchased, and the number of nursing visits furnished by the home infusion provider. Based on the type of therapy Mrs. Smith received, the plan makes a per diem payment for other components of her care (e.g., equipment and supplies, care coordination, and pharmacy services).</p>	<p>The health plan pays the home infusion provider the following amounts each week:</p> <table style="margin-left: 20px;"> <tr> <td style="padding-right: 10px;"><b>\$100</b></td> <td>for the vancomycin and infusion-associated drugs such as heparin</td> </tr> <tr> <td style="padding-right: 10px;"><b>\$ 85</b></td> <td>for each nursing visit, not to exceed 2 hours</td> </tr> <tr> <td style="padding-right: 10px;"><b>+ \$490</b></td> <td>(\$70 per diem for other components x 7 days of treatment)</td> </tr> <tr> <td style="padding-right: 10px;"><b>\$675</b></td> <td><b>per week</b></td> </tr> </table> <p>The health plan would pay the following amount for four weeks of treatment:</p> <table style="margin-left: 20px;"> <tr> <td style="padding-right: 10px;"><b>\$675</b></td> <td>per week</td> </tr> <tr> <td style="padding-right: 10px;">x <u>4</u></td> <td>weeks</td> </tr> <tr> <td style="padding-right: 10px;"><b>\$2,700</b></td> <td><b>total</b></td> </tr> </table>	<b>\$100</b>	for the vancomycin and infusion-associated drugs such as heparin	<b>\$ 85</b>	for each nursing visit, not to exceed 2 hours	<b>+ \$490</b>	(\$70 per diem for other components x 7 days of treatment)	<b>\$675</b>	<b>per week</b>	<b>\$675</b>	per week	x <u>4</u>	weeks	<b>\$2,700</b>	<b>total</b>
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<b>\$675</b>	per week														
x <u>4</u>	weeks														
<b>\$2,700</b>	<b>total</b>														

Source: GAO.

The health insurers in our study reported using these pricing data in different ways. For one insurer, plans in some states base payments on ASP while plans in other states base payments on AWP. Another insurer reported that its MA plans pay for Part D drugs using AWP or WAC, and pay for Part B drugs using either AWP for in-network providers or ASP plus 6 percent for out-of-network providers.

Most of the health insurers we spoke with also use a fee schedule to pay for nursing services.<sup>37</sup> The nursing fee schedule generally contains one rate for the first 2 hours of care and another rate for each subsequent hour. According to industry officials, insurers may also provide extra payment for nurses traveling to remote areas or areas considered dangerous enough to require an escort.

<sup>36</sup> Medicare pays for most other Part B drugs based on the lesser of the actual charge or 106 percent of ASP. See 42 C.F.R. § 414.904 (2009). For more information on Medicare payments for Part B drugs, see GAO, *Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain*, [GAO-06-971T](#) (Washington, D.C.: July 13, 2006).

<sup>37</sup> One insurer we interviewed generally includes nursing services in the per diem payment.

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Nursing services generally are not required for every dose of an infused drug, and the need for such services may depend on the condition of the patient. To explore this, we asked our selected health insurers to estimate nursing costs for different hypothetical cases.

- For a typical 4-week antibiotic infusion therapy course, insurers estimated the cost of nursing services would range from \$270 to \$384.
- For TPN administered over 12 hours, once a day over 4 weeks, insurers' estimates of the cost of nursing services ranged from \$180 to \$384.

Most of the health insurers in our study pay for the other components associated with home infusion therapy using a bundled payment per day of therapy—known as a “per diem.”<sup>38</sup> This daily rate may cover services, such as pharmacy services, equipment and supplies, and care coordination. The per diem payment amount is based on the type of therapy provided and varies depending on the complexity and frequency of the treatment. For example, the per diem payment for a simple infusion administered once a day might be \$75, whereas the per diem for a daily complex infusion with multiple drugs might be \$225.

Two of the health insurers we spoke with noted that the industry is trending toward greater use of bundled payments, with more services and supplies incorporated into a single rate. For one common home infusion therapy—TPN—the per diem also includes the standard drug costs. Asked about the costs of a typical monthlong course of TPN, insurers estimated total costs ranging from about \$3,400 to \$5,500, and noted that the per diem payments accounted for more than 90 percent of these costs.

Some health insurers we interviewed stated that the infusion drug is generally the most expensive component of home infusion therapy, while others reported most home infusion drugs were among the least expensive, such as generics. Some insurers reported that many of the infusion drugs they cover are specialty drugs that cost more than \$600 a

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<sup>38</sup>Health insurers use a uniform set of reimbursement codes for the per diem payment. These standard codes—known as “S codes”—were among those developed to meet the requirements of the Health Insurance Portability and Accountability Act of 1996. The act required HHS to adopt standard code sets for describing health-related services in connection with financial and administrative transactions, and required members of the health care industry to use these code sets.



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month.<sup>39</sup> Other drugs would cost less. For example, for a typical case of a month of antibiotic infusion therapy, a health plan could pay a home infusion provider \$300 for the drugs, \$350 for nursing services, and \$2,000 for the per diem. One insurer told us that the pace of development in specialty infusion drugs is accelerating, which could add to home infusion therapy costs.

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## Health Insurers Employ Standard Industry Practices to Manage Utilization of Home Infusion Therapy and Ensure Quality

Most of the health insurers in our study—both commercial and MA plans—use standard industry practices to manage utilization of home infusion and ensure quality of services for their members. None of the insurers reported significant problems with improper payments for home infusion therapy services.<sup>40</sup> While none of the insurers identified significant quality of care problems related to home infusion therapy, they all employ certain practices to help ensure care delivered meets quality standards.

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<sup>39</sup>The majority of specialty drugs are infusible or injectible drugs, according to a recent study. Nearly a third of all infusible or injectible drugs are on a specialty tier in at least one Part D prescription drug plan while only 1 in 10 pills are on specialty tiers. E. Hargrave, J. Hoadley, and K. Merrell, *Drugs on Specialty Tiers in Part D* (Washington, D.C.: Medicare Payment Advisory Commission, 2009).

<sup>40</sup>Improper payments include those for services not covered, not medically necessary, or billed but never actually provided. They can result from inadvertent errors as well as fraud and abuse. Inadvertent errors are often caused by clerical mistakes or a misunderstanding of program rules, whereas fraud is an intentional act of deception to benefit the provider or another person. Abuse typically involves actions that are inconsistent with acceptable business and medical practices.

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## Health Insurers Use Prior Authorization and Postpayment Claims Review to Manage Utilization of the Home Infusion Therapy Benefit

Most health insurers we interviewed use two standard industry practices—prior authorization, postpayment claims review, or both—to manage utilization of home infusion therapy for their members.<sup>41</sup> To obtain prior authorization, providers must request and receive approval from the health plan before the therapy is covered.<sup>42</sup> The plan typically requires providers to submit patient information in advance to support a request for coverage and receive payment authorization. With postpayment review, once a claim has been processed, the plan determines if it was billed and paid appropriately, and if not, the plan may seek a refund or adjust future payments.<sup>43</sup> Generally, a health plan auditor would review a sample of claims to see if the patients had medical conditions for which the proposed treatment was required. None of the insurers reported significant problems with improper payments for home infusion therapy.<sup>44</sup>

Most of the insurers we interviewed use prior authorization to curb inappropriate use of home infusion therapy.<sup>45</sup> Some insurers stated that prior authorization is particularly effective in managing the use of more costly infusion drugs. Some insurers stated that their plans limit their prior authorization requirement to certain home infusion therapies and drugs.<sup>46</sup> For example, certain hemophilia drugs may require prior authorization

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<sup>41</sup>Health insurers also told us that provider education was an important and effective tool, in terms of informing providers of both coverage and payment guidelines and appropriate medical indications.

<sup>42</sup>Prior authorization is one of the front-end management approaches that we have previously found may help manage Medicare FFS spending growth for imaging services. See GAO, *Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices*, [GAO-08-452](#) (Washington, D.C.: June 13, 2008).

<sup>43</sup>CMS, through its payment contractors, employs an array of retrospective payment safeguards in Medicare intended to help ensure payment accuracy.

<sup>44</sup>All of the health insurers we interviewed stated that they have not experienced any serious problems with fraud or abuse in home infusion therapy. There were several high-profile cases of fraudulent Medicare claims for infusion therapy in recent years, but they occurred in outpatient clinics rather than in home settings.

<sup>45</sup>A large insurer reported that it requires prior notification rather than prior authorization for some home infusion drugs. Providers must inform the patient's health plan before initiating treatment.

<sup>46</sup>To prevent the overuse of expensive medications, some Part D sponsors require lower-tier drugs to be tried first. See GAO, *Medicare Part D: Plan Sponsors' Processing and CMS Monitoring of Drug Coverage Requests Could Be Improved*, [GAO-08-47](#) (Washington, D.C.: Jan. 22, 2008).

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because they are expensive and patient needs vary substantially. Additionally, insurers may require prior authorization for immune globulin, checking that patients' medical conditions indicate use of the drug. In contrast, one home infusion expert told us that prior authorization has little utility for this type of therapy because home infusion providers would incur too much liability risk if they treated patients who were not appropriate for that setting.

The denial rates for prior authorization requests are reportedly low. A common reason given for denial of a prior authorization request was that the therapy did not meet medical necessity requirements.<sup>47</sup> Specifically, the requested coverage may be for a treatment of longer than the recommended duration or for a type of narcotic that may not be safe for administration in the home. Another common reason cited for prior authorization denials was insufficient documentation from the prescribing physician. Insurers also cited denials for drugs prescribed for off-label use—that is, for conditions or patient populations for which the drug has not been approved, or for use in a manner that is inconsistent with information in the drug labeling approved by the Food and Drug Administration. An insurance official stated that some conditions that are difficult to treat or diagnose do not have a universally accepted treatment approach. For example, two insurers cited denials for requests to treat Lyme disease with long antibiotic courses that were not supported by medical evidence.

Most health insurers we interviewed use postpayment claims review, some in addition to prior authorization, to manage the use of home infusion therapy. One insurer considered postpayment review the practice most effective in deterring inappropriate use of home infusion therapy. Such reviews may have a sentinel effect, meaning that providers who have erroneous claims returned may be less likely to submit such claims in the future. That insurer and an industry expert also noted the importance of developing very specific reimbursement guidelines for providers. An industry expert recommended guidelines at the dosage and package level, noting that a single infusion drug may be used for many different diagnoses, with a different dosage regimen for each diagnosis, and

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<sup>47</sup>These insurers said that their prior authorization criteria were based on reviews of clinical guidelines or research from current medical literature. For example, to determine whether drug-specific coverage criteria have been met, insurers may look for citations in drug reference guides to see if research supports using the drug for the prescribed indication.

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different package sizes from different manufacturers. For example, to reduce wasteful spending, reimbursement guidelines could include the specific package sizes that are covered for products that cannot be reused after they are opened.

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### Health Insurers Use Provider Networks, Accreditation, and Complaint Monitoring to Ensure Quality in Home Infusion Therapy

While none of the health insurers we spoke with identified significant quality problems related to home infusion therapy, they all employ certain practices to help ensure that their members receive quality care. These include developing a limited provider network of infusion pharmacies and home health agencies, requiring provider accreditation, coordinating care among providers, and monitoring patient complaints.

Most health insurers we interviewed create a network by contracting with a set of home infusion providers and suppliers that meet certain participation criteria, such as adherence to specified industry standards and licensure. One insurer's participation criteria contain a set of standards, including staffing requirements, guidelines for patient selection, and the ability to initiate therapy within 3 hours of a referral call. The infusion providers that insurers include in their networks range in size and may include large national chain providers and stand-alone local home infusion providers.

Health insurers told us they rely on credentialing, accreditation, or both to help ensure that plan members receive quality home infusion services from their network providers. Home infusion accrediting organizations conduct on-site surveys to evaluate all components of the service, including medical equipment, nursing, and pharmacy. The three accreditation organizations in our study reported that their standards include CMS Conditions of Participation for home health services,<sup>48</sup> other government regulations, and industry best practices. All of their accreditation standards evaluate a range of provider competencies, such as having a complete plan for patient care, response to adverse events, and implementation of a quality improvement plan. According to accreditation organizations we interviewed, an increasing number of providers are seeking home infusion-specific accreditation. One insurer told us that home infusion has minimal quality issues due to strong oversight of

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<sup>48</sup>Conditions of Participation are minimum health and safety standards that health care organizations and providers must meet in order to begin and continue participating in the Medicare and Medicaid programs.

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pharmacies through state and federal regulation and by accrediting institutions.

Accrediting organizations identified unique safety and quality factors that must be considered when providing infusion therapy in the home setting. First, home infusion providers must carefully evaluate the willingness and ability of the patient, caregiver, or both to begin and continue home therapy. Because infusion drugs are administered directly into a vein, the effect of a medication error is greater and faster in infusion therapy than with oral treatments. Providers must therefore also take steps to ensure that patients can recognize the signs and symptoms of an emergency. Second, providers must ensure that patients have the appropriate infrastructure in the home to store equipment, drugs, and supplies, and to provide the therapy. Needed infrastructure often includes a refrigerator to store infusion drugs and sometimes safeguards to protect patients' drugs and supplies, particularly in the case of controlled substances such as narcotics. Home infusion providers must have emergency support services available 24 hours a day, 7 days a week in case of an adverse drug reaction or to troubleshoot any problems with equipment, such as infusion pumps. Officials from one accrediting organization told us that they also expect infusion providers to have plans in place to deal with other types of emergencies, such as a natural disaster.

While officials from accrediting organizations did not report any pervasive quality issues, they described several common problems among home infusion providers that demonstrate the complexity of the treatment. Home infusion providers may not have staff with the appropriate training and competencies, which may be a challenge for small organizations. Also, they may inadequately coordinate care for patients who receive multiple medications and have multiple physicians. Furthermore, home infusion providers may not always meet documentation and planning requirements for accreditation. For example, officials from one accrediting organization stated that the top two deficiencies for infusion companies are incomplete plans of care and a lack of a comprehensive quality improvement program.

In addition, home infusion providers may find it challenging to meet some technical standards, including pharmaceutical requirements. An accrediting official observed that some infusion pharmacies are still learning to comply with recent industry standards for combining ingredients or other processes to create a drug in a sterile environment. Poor procedures to track recalled items is another common technical deficiency for home infusion providers. Providers generally have recall

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processes for medications, but sometimes not for every item used in the provision of care, as required by that accreditation organization.

Communication and coordination of care between multiple entities is particularly important for this type of treatment. Several of the insurers we interviewed have processes to coordinate care for home infusion therapy and told us that they take responsibility for that function. Others rely on the patient's physician, home infusion provider, discharging facility, or a combination of these to coordinate care. Two of the health insurers use the prior authorization process to coordinate care, as case managers initiate contact with the member and home infusion provider and follow up throughout the duration of the therapy.

In addition to policies and procedures related to quality, all of the health insurers and accreditation organizations we interviewed have a process for addressing patient complaints. None of the health insurers told us that they have received significant complaints related to home infusion. One insurer cited a case in which a specialty pharmacy had diluted drug doses, and suggested that such problems concerning the quality and integrity of drugs could be overcome with information technology, such as bar coding of drugs.

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## Conclusions

Due to the limited coverage of home infusion therapy under Medicare FFS and some MA plans, non-homebound beneficiaries would need to obtain treatment in alternate and potentially more costly settings—such as a hospital, outpatient department, or physician's office—to have all of the components of infusion therapy covered. All of the health insurers in our study provide comprehensive coverage of home infusion therapy for all members in their commercial health plans, and some do so in their MA plans as well. Health insurers contend that the benefit has been cost-effective, that is, providing infusion therapy at home generally costs less than treatment in other settings. They also contend that the benefit is largely free from inappropriate utilization and problems in quality of care. Given the long and positive experience health insurers reported having with home infusion therapy coverage, further study of potential costs, savings, and vulnerabilities for the Medicare program is warranted.

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## Recommendation for Executive Action

The Secretary of HHS should conduct a study of home infusion therapy to inform Congress regarding potential program costs and savings, payment options, quality issues, and program integrity associated with a comprehensive benefit under Medicare.

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## Agency and Other External Comments and Our Evaluation

We obtained comments on a draft of this report from HHS and from the National Home Infusion Association, a trade group representing organizations that provide infusion and specialized pharmacy services to home-based patients. HHS provided written comments, which are reprinted in appendix I. Officials from the trade association provided us with oral comments.

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### HHS Comments

HHS stated that Medicare covers infusion therapy in the home for beneficiaries who are receiving the home health benefit; other beneficiaries have access to infusion therapy in alternate settings, such as hospitals, outpatient departments, and physician offices. HHS noted that adding home infusion therapy as a distinct Medicare benefit would require a statutory change, and suggested we modify our recommendation to recognize statutory authority would be required. To make this more clear, we have rephrased our recommendation for executive action.

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### National Home Infusion Association Comments

National Home Infusion Association officials stated that few beneficiaries, even among those who are homebound, receive infusion therapy outside their homes due to the gaps in Medicare FFS coverage. They told us that Medicare FFS does not cover care coordination and clinical monitoring services when performed by infusion pharmacists—the providers most familiar with infusion drugs and treatment regimens. The officials said that homebound beneficiaries, therefore, would not receive infusion therapy in their homes without having supplemental coverage or paying out-of-pocket for services provided by an infusion pharmacist.

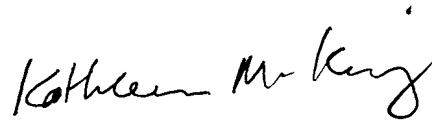
However, CMS officials reported that infusion therapy in the home is largely provided through home health agencies, which are responsible for meeting a range of beneficiaries' care needs. These agencies may perform care coordination and clinical monitoring functions themselves or arrange for these services from an independent infusion provider, according to CMS and a home health provider organization. In either case, these services are covered and paid for under the Medicare home health benefit.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the CMS Administrator, and interested congressional committees. The report also will be available at no charge on GAO's Web site at <http://www.gao.gov>.

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If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or [kingk@gao.gov](mailto:kingk@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made major contributions to this report are listed in appendix II.



Kathleen M. King  
Director, Health Care



# Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

MAY 24 2010

Kathleen King  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

Dear Ms. King:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Home Infusion Therapy: Differences Between Medicare and Private Insurers' Coverage" (GAO-10-426).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Palm", written over a horizontal line.

Andrea Palm  
Acting Assistant Secretary for Legislation

Enclosure

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) TO THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "HOME INFUSION THERAPY: DIFFERENCES BETWEEN MEDICARE AND PRIVATE INSURERS' COVERAGE" (GAO-10-426)**

The Department appreciates the opportunity to review and comment on this GAO draft report.

Medicare covers home infusion therapy drugs and services for Medicare beneficiaries who are receiving the home health benefit. Beneficiaries who are not receiving the home health benefit have access to infusion therapy services and drugs in hospitals, outpatient departments and physician offices.

The draft report summarizes coverage of home infusion therapy under Medicare and private insurers. GAO recommends that the Secretary conduct a study of the potential cost-effectiveness of establishing comprehensive home infusion therapy coverage for all Medicare beneficiaries. Since adding home infusion therapy as a distinct benefit to the Medicare program would require a statutory change, we recommend that GAO change its recommendation in the report to say, "GAO recommends that the Secretary should conduct an analysis of the program costs and the implications on quality and fraud and abuse controls if Congress were to consider adding home infusion therapy as a distinct benefit under the Medicare program."

We thank the GAO staff for their work in this important area and the Office of the Assistant Secretary for Legislation for the opportunity to comment.

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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

Kathleen M. King, (202) 512-7114 or [kingk@gao.gov](mailto:kingk@gao.gov)

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## Acknowledgments

In addition to the contact named above, Rosamond Katz, Assistant Director; Jennie F. Apter; Jessica T. Lee; Drew Long; Kevin Milne; and Julie T. Stewart made key contributions to this report.

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