

CHAPTER

6

**Medicare coverage of
and payment for
home infusion therapy**

Medicare coverage of and payment for home infusion therapy

Chapter summary

The Congress requested that the Commission conduct a study on home infusion therapy and report its findings by June 2012. The Commission was asked to look at the benefits and costs associated with providing infusions in the home versus alternative settings, coverage and payment for home infusion therapy by commercial insurers and Medicare Advantage plans, potential abuse of a home infusion therapy benefit, and the possibility of achieving savings through avoided or shortened hospital or nursing home stays as a result of Medicare coverage of home infusion therapy.

Home infusion involves the intravenous administration of drugs to an individual at home. The components needed to perform a home infusion include the drug (e.g., antibiotics, immune globulin), equipment (e.g., a pump or a pole), and supplies (e.g., tubing and catheters). Visiting nurses may play a role in home infusion. For antibiotics, nurses typically train the patient or caregiver to administer the drug independently and visit periodically to provide catheter care. Some drugs require more nursing time.

The home infusion process requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion providers, and home health agencies. We found broad differences in how the process is managed, with possible consequences for patient care when coordination does not occur.

Traditional fee-for-service (FFS) Medicare generally covers some or all components of home infusion depending on the circumstances. Drugs are

In this chapter

- Provision of home infusion by private health plans, MA plans, and other payers
- Medicare beneficiary experience
- Potential for abuse of a Medicare home infusion benefit
- Assessment of cost data
- Cost implications of expanded home infusion coverage in Medicare
- Design considerations for expanded home infusion coverage in Medicare
- Conclusion

generally covered under Part B or Part D. Supplies, equipment, and nursing are covered in some circumstances through the Part B durable medical equipment benefit, the prosthetic benefit, the Medicare home health benefit, or some combination of these benefits. Infusion services are available to beneficiaries in several settings in addition to the home. FFS Medicare covers drugs and drug administration services in physician offices and hospital outpatient departments. Drugs and drug infusion services are generally included in the bundled payment made to inpatient hospitals and skilled nursing facilities under the prospective payment systems.

The specific questions the Congress asked the Commission to examine and the study's findings concerning these issues are:

1. An assessment of the literature relating to the benefits and costs of providing coverage for home infusion therapy under the Medicare program, including an assessment of the possibility of achieving savings through avoided or shortened hospital or nursing home stays as a result of Medicare coverage of home infusion therapy

Though there is some literature on the costs of home infusion, most studies are dated and do not estimate the costs of a home infusion program under Medicare's FFS payment systems. Based on our analysis, whether home infusion yields Medicare savings or costs for an individual beneficiary depends on the setting where the beneficiary otherwise would have received infusions, the payment rates established for home infusion and how they compare with the payment rates in that alternative setting, how frequently the drug is infused, and how often home nurse visits are needed. To the extent that some beneficiaries are admitted to skilled nursing facilities because of the out-of-pocket costs associated with home infusion, opportunities likely exist to achieve savings by providing care for these beneficiaries in their homes. Shifting infusions from hospital outpatient departments or physician offices to the home could yield net savings or costs depending on how frequently nurse visits are needed, how drug payment rates compare under Medicare Part B and Part D, and the payment rates established for home infusion. Savings from substituting home infusion for home health episodes may be possible in some circumstances. Inpatient hospital expenditures are not likely to be a significant source of savings because we do not anticipate substantial substitution of home infusion for hospital admissions. Some patients might be discharged earlier from the hospital as a result of broader coverage for home infusions, but the impact on Medicare expenditures for such patients would vary, with savings expected for a small subset and little change or increased expenditures expected for most.

For expanded coverage of home infusions to realize overall savings for Medicare, shifts in site of service would need to result in savings that exceed the additional costs associated with the crowd-out effect (i.e., Medicare assuming responsibility

for home infusion services that otherwise would have been paid by other insurers or beneficiaries) and the woodwork effect (i.e., coverage of home infusion leading to more beneficiaries using intravenous drugs who otherwise would have been treated with other therapies). The cost implications of broader coverage of home infusions vary by drug. As a result, a targeted expansion of home infusion coverage focusing on a subset of drugs would have more likelihood of savings than a broad expansion. However, a lack of data impairs our ability to determine whether net savings would result, even in the case of a targeted expansion (e.g., antibiotics, or intravenous immune globulin for primary immune deficiency). Although it is unsatisfactory to be unable to draw a conclusion about net savings or costs, it might be possible to collect additional information to fill in some of the data gaps, but it would be difficult to collect all the data needed.

2. An assessment of sources of data on the costs of home infusion therapy that might be used to construct payment mechanisms in the Medicare program

Data on the cost associated with providing home infusion services are very limited. An industry-sponsored study that estimated the per diem costs of home infusion has methodologic limitations that reduce its utility for rate setting. Data on Medicare payment rates for similar services, such as home health or durable medical equipment, might be a source of some benchmarks. Another avenue for obtaining cost information might be competitive bidding. Also, the feasibility of obtaining data on providers' acquisition costs or manufacturers' sales prices for equipment and supplies could be explored.

3. An assessment of private payment methodologies used by Medicare Advantage plans and private health plans for the provision of home infusion therapy and their applicability to the Medicare program, with reference to recent work by the Government Accountability Office

We found that the most common payment method used by private health plans and Medicare Advantage plans included a payment for drugs, a separate payment for nursing as needed, and a per diem amount covering supplies, equipment, pharmacy services, and additional services. The Government Accountability Office did not discuss the applicability of this payment method to Medicare. This payment method could be applicable to Medicare depending on the payment rate chosen. Providers we interviewed described a wide range of payment levels for per diem services. Other payment methods may be possible, including bundling (as part of an episode of care or bundling nursing along with supplies and equipment as part of a per diem payment) and competitive bidding.

Some technical issues would have to be resolved with any methodology selected. For example, some drugs are covered under Part B or Part D, using different

payment methods. Services covered under the Part D dispensing fee overlap with some of the services provided under the per diem paid by private plans. In designing a payment method, policymakers would also need to be cognizant of the potential for increased expenditures because of a crowd-out effect and a woodwork effect.

4. A discussion of any issues surrounding the potential abuse of a home infusion therapy benefit in Medicare

Private plan representatives did not report any evidence that fraud and abuse are more prevalent in the area of home infusion than in any other type of service. All plans apply utilization management techniques, particularly prior authorization, to ensure that home infusion is provided appropriately. Plans generally ask physicians to report the diagnosis, prescribed drug, dosage, and expected duration of therapy. They may also request information about the patient's age, sex, and weight. Some plans require separate approval for a schedule of nursing visits. One health plan described the need to look closely at home infusion utilization to ensure it is appropriate and noted that this kind of oversight would present a challenge for FFS Medicare. In general, Medicare has had less ability to monitor care provided in the home than in facility settings and it has been more difficult to create payment systems with incentives for appropriate utilization. While private payers have not found fraud to be a problem in the home infusion industry, a broad, unmanaged expansion of Medicare FFS coverage could lead to fraudulent actors entering the field.

Although we did not make any recommendations, we discussed two approaches for increasing access to home infusion: filling in the gaps in current coverage and setting up a demonstration project to test the effects of providing an integrated home infusion benefit for beneficiaries needing infused antibiotics. Each approach has advantages and drawbacks. We examined the gap-filling approach by considering policies for intravenous immune globulin under Part B and antibiotics under Part D. We examined the integrated benefit approach through a demonstration project that would test quality and efficiency under an integrated home infusion benefit for antibiotics.

To ensure appropriate utilization, a project testing provision of a home infusion therapy benefit would require management controls such as prior authorization. This project could test the ability of CMS to administer a targeted prior authorization policy designed to improve quality of care and reduce costs. Since prior authorization can be labor intensive and require considerable resources, it would be a challenge for CMS. However, targeted prior authorization could be a useful tool to improve quality and control inappropriate utilization not just in home infusion but in other areas as well. If CMS is able to administer a targeted prior authorization program, benefits would accrue to beneficiaries and the program as a whole. ■

Background

The Congress requested that the Commission conduct a study on home infusion therapy and report its findings by June 2012. The Commission was asked to look at issues such as the benefits and costs associated with providing infusions in the home versus alternative settings, how commercial insurers and private plans cover and pay for home infusion therapy, and potential issues surrounding fraud and abuse.

Scope of the study request

The Commission was asked to examine:

- literature relating to the benefits and costs of providing coverage for home infusion therapy under the Medicare program, including an assessment of the possibility of achieving savings through avoided or shortened hospital or nursing home stays as a result of Medicare coverage of home infusion therapy;
- sources of data on the costs of home infusion therapy that might be used to construct payment mechanisms in the Medicare program;
- payment methodologies used by Medicare Advantage (MA) plans and private health plans for the provision of home infusion therapy and their applicability to the Medicare program, with reference to recent work by the Government Accountability Office (GAO); and
- any issues surrounding the potential abuse of a home infusion therapy benefit in Medicare.

In addition, the Commission was asked to submit recommendations for Medicare's coverage of and payment for home infusion therapy if warranted by the Commission's research.

Study design

To perform our study, we contracted with Acumen, LLC, to analyze data on Medicare's current expenditures on home infusion; contracted with NORC to interview health plans, home infusion therapy providers, hospital discharge planners, state Medicaid programs, and physicians; and conducted additional interviews with physicians, home health agencies, and others with expertise in this area. We also conducted a literature review of studies looking at the benefits and costs of home infusion, developed a conceptual framework of the possible effects expanded

coverage of home infusion could have on Medicare expenditures, and presented some illustrative scenarios in which broader Medicare coverage of home infusion may yield savings or additional expenditures compared with infusion in other settings. We also explored the advantages and disadvantages of policies designed to increase home infusion coverage, including filling in current coverage gaps and designing a demonstration project to test the quality and efficiency of providing an integrated home infusion benefit for antibiotics.

What is home infusion?

Home infusion involves the intravenous (IV) administration of drugs to individuals in their homes.¹ The components needed for home infusion include the drug (e.g., antibiotics, immune globulin), equipment (e.g., pump, pole), and supplies (e.g., tubing and catheters). Visiting nurses are often involved in home infusion. From our discussions with home infusion providers and health plans, we have heard that the nurse's role in home infusions in most situations is to train the patient or family to administer the infusion. Often a nurse is present at the initial or first few infusions until the patient or family member is properly trained; thereafter the nurse visits periodically to check the infusion site and provide catheter care. (Some drugs may require more nursing assistance.) Home infusion is often described as being more convenient for patients than traveling to a health care provider's office for infusions, particularly when infusions are needed every day or multiple times a day.

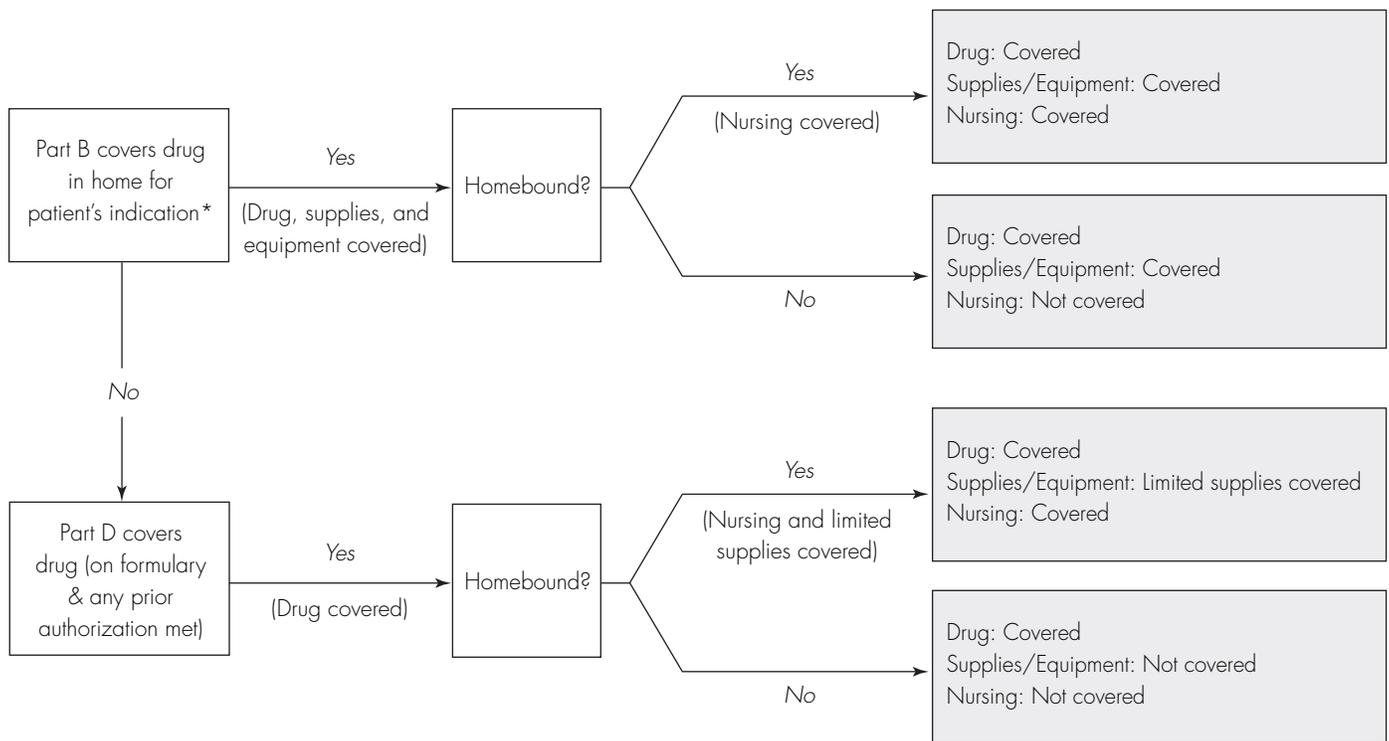
Medicare covers infusions in a number of settings in addition to the home. Traditional fee-for-service (FFS) Medicare covers drugs and drug administration services in physician offices and hospital outpatient departments (HOPDs). Infusion services are also covered in inpatient settings, such as acute care hospitals and skilled nursing facilities (SNFs), and are generally bundled into the payments these providers receive.²

Medicare's current coverage of home infusion

Medicare covers the various home infusion therapy components across several separate payment systems (Figure 6-1, p. 176). Drug coverage is the broadest component, falling under Medicare Part B and Part D. Supplies, equipment, and nursing services are covered in certain circumstances under FFS Medicare through the durable medical equipment (DME), prosthetic, and home health benefits. Some MA plans provide broad coverage of

FIGURE 6-1

Medicare fee-for-service coverage of home infusion



Note: A beneficiary who is homebound and who needs part-time or intermittent skilled nursing assistance with home infusion of intravenous drugs would generally meet the Medicare home health benefit eligibility criteria, in which case nursing and in some circumstances limited supplies would be covered. If the drug is not covered by Part B or Part D, a homebound beneficiary would potentially have coverage under the home health benefit for nursing and in some circumstances certain supplies, but not the drug or equipment.

*Intravenous immune globulin covered in the home under Part B follows different coverage rules than displayed above (only the drug is covered unless the beneficiary is homebound, in which case nursing and, in some circumstances, limited supplies are covered).

Source: MedPAC analysis of Medicare coverage rules.

home infusion, particularly those that bundle Part D home infusion drugs with equipment, supplies, and nursing under Part C as a mandatory supplemental benefit.

In some situations, FFS Medicare covers all home infusion components (drugs, equipment, supplies, and nursing), whereas in other situations it covers only some components. Coverage of home infusion components depends generally on whether the drug is covered under Part B or Part D and whether the beneficiary is homebound.³ If the drug is covered under Part B (except in the case of IV immune globulin (IVIG)), the drugs, supplies, and equipment are generally also covered by Part B.⁴ In contrast, Part D covers only the home infusion drug. For homebound beneficiaries, the home health benefit provides nursing services and limited supplies. If

the beneficiary is not homebound, FFS Medicare does not cover nursing.

If Medicare does not cover a certain component of home infusion services, some beneficiaries have coverage through employer-sponsored supplemental insurance or Medicaid. Individually purchased medigap policies do not cover these services. Beneficiaries facing out-of-pocket costs for home infusion may choose to receive infusion services in another setting, such as a SNF, physician office, or HOPD, or they may decide to pay out of pocket for certain home infusion components.

Medicare Part B drug coverage

DME drugs Medicare Part B covers a small number of home infusion drugs through the DME benefit. To be covered under the Part B DME benefit, the drug must

require administration using a DME infusion pump and administration of the drug in the home must be medically reasonable and necessary. The DME Medicare administrative contractors limit this coverage to about 30 drugs specified in their local coverage policies (Centers for Medicare & Medicaid Services 2011). Examples include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy in limited circumstances. Medicare pays for these drugs based on 95 percent of the October 1, 2003, average wholesale price (AWP) (or, for new drugs, 95 percent of the products' initial AWP) until these drugs come under competitive bidding.⁵ These drugs have not been proposed for inclusion in competitive bidding thus far.

IVIG in the home By special statutory provision, Medicare Part B also covers IVIG administered in the home (which does not require a DME pump according to CMS policy) for patients with PID. Medicare pays for IVIG in this situation based on 106 percent of the average sales price (ASP).

Parenteral nutrition Through the prosthetic benefit, Medicare Part B also covers total parenteral nutrition (TPN, or more commonly, IV nutrition) for patients with a permanently nonfunctioning gastrointestinal tract. Medicare pays for TPN according to a fee schedule.

Medicare Part D drug coverage

Any infusion drug that is not covered under Part B is potentially a Part D drug subject to the plan's formulary and any medical necessity or prior authorization criteria. For example, Medicare Part B does not cover antibiotics for home infusion because CMS has determined they do not require a DME pump. Therefore, IV antibiotics may be covered under Part D. As another example, Part B covers home infusion of IVIG for beneficiaries with PID. Beneficiaries with a diagnosis other than PID could, depending on the plan, receive coverage for home infusion of IVIG under Part D.

Part D plans are required to contract with home infusion pharmacies to provide access to home infusion drugs to their enrollees. CMS has access requirements in terms of the number of home infusion pharmacies a plan must contract with in a state. Part D provides coverage only for the drug; it does not cover the equipment, supplies, and nursing services associated with home infusions. However, Part D plans are required to ensure that the network

pharmacies they contract with verify that the necessary equipment, supplies, and services are present to support home infusion before dispensing a drug covered by Part D for home infusion. They must also provide the drug in a form that can be administered by a patient or caregiver.

Equipment and supplies

FFS Medicare covers equipment and supplies associated with home infusions in certain circumstances. For DME-covered drugs and TPN covered under the prosthetic benefit, Medicare Part B covers the associated equipment and supplies. For other home infusion drugs (i.e., drugs covered by Part D or IVIG covered by Part B), the Medicare home health benefit covers limited supplies, such as alcohol swabs, if the beneficiary meets the Medicare home health eligibility criteria and receives the infusion via the gravity method (not a pump).

Nursing

Nursing services for home infusion are covered only for FFS Medicare beneficiaries receiving the home health benefit. To qualify for home health care, a beneficiary must be homebound and need skilled care, such as part-time or intermittent skilled nursing care. Thus, beneficiaries meeting the homebound requirement who need nursing services related to home infusion generally qualify for the Medicare home health benefit.

Medicare Advantage coverage of home infusion

Some MA plans provide broad coverage for home infusion. MA plans have the option of bundling Part D home infusion drugs with equipment, supplies, and nursing services under Part C as a supplemental benefit. In this situation, the MA plan is not permitted to charge cost sharing for the bundled home infusion services. As of 2009, about 219 MA plans with enrollment of about 1.5 million beneficiaries (accounting for about 15 percent of MA enrollees) bundled home infusions under Part C. Less is known about the extent of home infusion coverage for the majority of MA plans that provide home infusion drugs through Part D. While these plans have broader flexibility to cover supplies, equipment, and nursing under Part C than what is covered under FFS Medicare, we do not have data on the extent to which they provide such services.

Medicare's current expenditures on home infusion

A relatively small number of Medicare beneficiaries—about 36,000 FFS beneficiaries under Part B and just

**TABLE
6-1****Top three home infusion drugs covered by Part B and Part D, 2009**

Home infusion drug or drug class	Part B/Part D drug spending (millions)	Percent of Part B/Part D home infusion spending	Number of users	Percent of Part B/Part D home infusion users	Average spending per user
Part B–covered drugs					
Parenteral nutrition	\$159.0	35%	4,745	13%	\$33,511
Treprostinil	123.6	27	977	3	126,490
Immune globulin	64.5	14	2,040	6	31,615
All Part B–covered drugs	453.2	100	36,314	100	12,479
Part D–covered drugs					
Immune globulin	139.6	33	2,007	2	69,541
Antibiotics	70.2	17	56,196	55	1,250
Alpha-1 proteinase inhibitor	68.8	16	843	1	81,607
All Part D–covered drugs	421.7	100	101,352	100	4,161

Note: Drug spending refers to program payments and beneficiary cost sharing for Part B and plan payments and beneficiary cost sharing for Part D. In the table, average spending per user does not precisely equal drug spending divided by number of users due to rounding.

Source: MedPAC analysis of results from Acumen, LLC, analysis.

over 100,000 Medicare beneficiaries under Part D—received home infusion drugs in 2009. Home infusion expenditures in Part B (including beneficiary cost sharing) for drugs, equipment, and supplies totaled about \$602 million (about \$453 million for drugs, \$83 million for supplies, and \$67 million for equipment). Part D plan payments and beneficiary cost sharing for IV drugs covered by Part D totaled about \$422 million in 2009.⁶ This amount does not include FFS spending for Medicare home health episodes that may have been triggered by a beneficiary’s need for home infusion, nor does it reflect spending by MA plans other than drug costs incurred under Part D.

Medicare spending on home infusion drugs and the number of beneficiaries receiving those drugs has grown rapidly since 2006. Medicare Part D gross costs for home infusion drugs grew at an average annual rate of 47 percent between 2006 and 2009. During this period, the number of Part D enrollees receiving Part D–covered home infusion drugs grew an average of 21 percent per year, far outpacing growth in the overall Part D population (which averaged 5 percent per year). During the same period, Medicare FFS spending for Part B–covered home infusion drugs increased at an average rate of about 17 percent per year, compared with an average annual growth rate of 6 percent in the number of beneficiaries using Part B home infusion drugs. This growth in Part B home

infusion drug use and expenditures occurred during a period when the Medicare FFS Part B population declined by about 1 percent per year.

Medicare expenditures on home infusion drugs are concentrated on a small number of products. IV antibiotics covered by Part D accounted for the largest number of users of Medicare-covered home infusion drugs. More than 56,000 beneficiaries used Part D–covered IV antibiotics in the home in 2009, with a gross drug cost of about \$70 million and an average gross drug cost per user of about \$1,250 (Table 6-1). (More detailed data on current Medicare expenditures for home infusion are available in an online appendix to this chapter (<http://www.medpac.gov>.) The remainder of Medicare spending on infusion drugs was largely concentrated on a few products with a very small number of users and a high cost per user. For example, under Part D, two drugs—immune globulin and alpha-1 proteinase inhibitor (with about 2,000 or fewer users each and annual gross drug costs per user averaging roughly \$70,000 to \$80,000)—accounted for half of Part D gross drug costs for IV drugs. In addition, several rheumatoid arthritis and antineoplastic drugs (infliximab, bevacizumab, and rituximab) with a high cost per user but a small number of users are among the top 10 IV drugs with the highest Medicare Part D expenditures (see online appendix to this chapter (<http://www.medpac.gov>)). (Part D data

do not include information on the diagnosis for which the drug is being prescribed.) About three-quarters of Medicare Part B spending on home infusion drugs was concentrated on three products (TPN, treprostinil, and immune globulin for PID) that had between just under 1,000 and 4,750 users each and Medicare drug expenditures per user averaging over \$30,000 to more than \$125,000.

Use of home infusion drugs varies by beneficiary and Part D plan characteristics. In 2009, the populations with the highest share of beneficiaries using Part D home infusion drugs were beneficiaries under age 65 or over age 85, those with end-stage renal disease, and minorities. Beneficiaries enrolled in the low-income subsidy and prescription drug plans (since these plans enroll a disproportionate share of low-income subsidy enrollees) were also more likely to use Part D home infusion drugs than their counterparts.⁷ Beneficiaries who were younger or had end-stage renal disease were more likely to use Part B home infusion drugs than other beneficiaries.

The degree to which the Medicare home health benefit is a source of coverage for nursing services associated with home infusions varies by drug. There is a high rate of home health use among beneficiaries who received IV antibiotics covered by Part D. For example, for the two highest expenditure Part D antibiotics in 2009, a home health nurse visit occurred within 6 days of the prescription being filled for 76 percent and 63 percent of prescriptions. Home health visits occurred within 6 days of the prescription being filled for 15 percent to 21 percent of prescriptions for immune globulin, alpha-1 proteinase inhibitor, and parenteral nutrition additives.

Provision of home infusion by private health plans, MA plans, and other payers

To understand how private payers, MA plans, and Medicaid cover and pay for home infusion, we contracted with NORC to conduct semistructured interviews with health plans, home infusion providers, and hospital discharge planners. Interviews included 15 health plans, 10 home infusion providers, 10 discharge planners, and 4 state Medicaid programs. The Commission or NORC staff also interviewed physicians in several specialties (infectious disease, immunology, cardiology, and pulmonology). Staff interviewed home health providers

and representatives from CMS and the Department of Veterans Affairs and met with stakeholders representing the industry and beneficiary advocates. In most cases, we could not independently validate the accuracy of their accounts or assess their generalizability.

In asking the Commission to assess how commercial insurers and MA plans cover and pay for home infusion therapy, and the applicability of those approaches to the Medicare program, the Congress asked us to build off a recent GAO study (Government Accountability Office 2010). Findings from the GAO study on home infusion are summarized in the text box (p. 180). Much of what we heard in interviews about how plans cover and pay for home infusion services and their utilization management and quality assurance approaches is similar to findings reported by GAO.

Clinical and administrative decisions regarding home infusion coverage

Patients who receive home infusion of antibiotics usually begin their spell of illness in the hospital. Under this scenario, the decision to prescribe home infusion generally begins with a conversation between a physician and a hospital discharge planner or case manager. In the case of antibiotics, patients with orthopedic joint infections, bone infections, cardiovascular endocarditis, and other postoperative infections are likely to require postdischarge antibiotics. If the physician determines that oral medications are not effective, the discharge planner—in consultation with the physician, patient, and patient’s insurer—determines the most appropriate site of care for a treatment regimen involving infused drugs. For patients requiring antibiotics, physicians and insurers generally told us that the home would be the optimum setting. Discharge planners report that patients also prefer this setting.

However, home infusion is not always appropriate. The decision to use it depends on the nature of the medication, patient and family characteristics, and insurer coverage rules.

- **Drug characteristics**—Interviewees’ opinions about drugs suitable for home infusion fell on a continuum, with some insurers limiting coverage to a few products and others identifying home infusion as their first choice whenever possible. As is the case under Medicare Part D, antibiotics were cited as the most common type of drug covered by home infusion in the commercial market. Other common

Report on home infusion by the Government Accountability Office

The Congress requested that the Government Accountability Office (GAO) review home infusion therapy coverage policies in the private market in relation to Medicare policy. In its June 2010 report, GAO reviewed Medicare fee-for-service coverage of home infusion and conducted interviews with health insurers, home infusion associations, one home infusion provider, a utilization management organization, and three organizations that accredit home infusion providers (Government Accountability Office 2010). GAO also reviewed the benefit packages submitted to CMS by Medicare Advantage (MA) plans.

GAO reported that the health plans interviewed cover home infusion therapy comprehensively in all their commercial benefit packages; two out of five provide similar comprehensive coverage under their MA plans. The health insurers GAO interviewed believed that home infusion was cost-effective relative to inpatient

settings. The cost savings were less clear when comparing infusion in the home with infusion in a physician office or an infusion clinic.

The insurers interviewed explained their methods for monitoring the utilization and quality of their home infusion benefit. GAO reported that most of the plans use prior authorization, postpayment claims review, or both to manage utilization of the benefit. The plans noted the importance of developing very specific reimbursement guidelines for providers. To ensure high quality, the plans interviewed used a limited provider network of infusion pharmacies and home health agencies, required accreditation, monitored patient complaints, and coordinated care among providers. The accrediting organizations further identified factors that indicate high-quality providers. GAO recommended further study of home infusion therapy to inform the development of a comprehensive benefit under Medicare. ■

products mentioned were TPN, hydration, antifungals, and IVIG. Interviewees rated drugs on the degree of risk they entailed. Factors mentioned as increasing risk included drugs requiring administration within a controlled and sterile environment, drugs with unpredictable adverse effect profiles, drugs with a short period of stability, drugs that must be given using a peripheral line, and regimens that include multiple drugs during the course of a day. Most insurers do not cover chemotherapy in the home because of the potential toxicity of the drugs, the need for multiple products, and unpredictable changes in therapy needs. At least one home infusion pharmacy mentioned that it will not cover products if reimbursement is below their costs. Accordingly, this agency no longer covers IVIG under Medicare Part B because they believe the payment rate (ASP plus 6 percent) does not cover their drug costs.

- **Patient characteristics**—Interviewees mentioned a wide variety of factors that determine whether a patient is a candidate for home infusion. The patient or a caregiver should be able and willing to administer the medication after initial education. (One health plan requires a nurse to be present for all home infusions.)

The patient's home must be clean and have reliable refrigeration, electricity, and water supply. The patient should be able to adhere to the medication regimen and not have a history of IV drug abuse. Some interviewees noted that patients in dysfunctional families may not be good candidates. If the patient has additional complex medical needs (e.g., multiple comorbidities), most interviewees did not consider home infusion appropriate.

- **Insurer coverage rules**—All interviewees reported that private payers tend to have broader coverage for home infusion than FFS Medicare. They generally cover supplies, equipment, pharmacy services, and nursing as well as drugs. However, insurer coverage varies by drug. For example, a number of health plans told us they did not cover IVIG in the home (for safety and financial reasons) and most did not authorize home infusion for chemotherapy. Many interviewees said that insurers authorize nursing visits at the same time they approve a drug regimen. Additional nursing visits may require further authorization. One provider told us that in her region commercial insurers use the Medicare definition of homebound to determine whether nursing visits

are covered. Most interviewees told us that home infusion was covered by Medicaid in their state and beneficiaries dually eligible for Medicare and Medicaid had no difficulty getting coverage.

Managing home infusion

The home infusion process requires coordination among multiple entities. Patients, physicians, hospital discharge planners, health plans, home infusion providers, and home health agencies all have roles to play. We found broad differences in how the process is managed, with possible consequences for patient care.

Role of the physician

Home infusion begins with a physician order, which includes the drug, dosage, frequency of administration, and expected duration of treatment. The physician works with the hospital discharge planner to initiate a referral to a home infusion provider.⁸ Although any physician may write the order, we noted multiple hospitals and health plans require input from an infectious disease specialist in the case of antibiotics. They are most likely to know if infused drugs are necessary and appropriate. One retrospective study examined the impact of infectious disease consults at the Cleveland Clinic over a three-month period in 2010. The most common diagnoses requiring consults were bone and joint infection, skin or soft tissue infection or rash, endocarditis or cardiac device infection, IV catheter or other endovascular infection, and urinary tract infection. The authors concluded that 27 percent of patients initially referred for community-based infusion of antibiotics before the consults did not require infused antibiotics. This number includes 16 percent of patients who did not require IV antibiotics and 11 percent of patients who did not require any antibiotic (Shrestha et al. 2011). Although the study was not designed to capture data on patients who would have benefited from IV antibiotics but did not receive them, it is possible that infused antibiotics are underused.

In some cases, the infectious disease physician continues to treat the patient after discharge and has primary responsibility for coordinating all patient care until the infection is controlled. When that does not happen, either because the patient lives too far away or because an infectious disease specialist was not involved, the treating physician may depend on the home infusion provider or home health agency to coordinate care for the infusion process. Some physicians were concerned that patient care suffered in those circumstances—for example,

when the initial order was written by a hospitalist and another physician took over the case after the patient was discharged. A number stressed the difficulty of coordinating care for nursing home residents because the home's medical director is in charge of all care for the residents.

In several instances, interviewees reported that physician office-based care minimized the need for separate nursing visits for patients receiving IV antibiotics. In these cases, patients see the physician once a week. During the visit, office-based nurses monitor lab results and clean and flush lines as needed, while the physician evaluates the patient's progress. In at least one instance, an interviewee reported that the patient is given the medication to take home, eliminating the need for delivery by a home infusion provider.

Role of the patient

A patient who needs infusion therapy may receive it in a number of settings, including the home, ambulatory infusion suites, physician offices, HOPDs, and SNFs. Patient choice plays a large role in the decision. Since most home infusion benefits assume that the patient or caregiver is administering the drug most of the time, patients must feel confident that they can do it. The home infusion patient must also be able to recognize adverse events and have access to reliable transportation to a clinic or hospital if needed.

Most interviewees told us that patients generally prefer receiving infusions in their homes and providers report high patient satisfaction. Research generally supports this view (Paladino and Poretz 2010). Bernard and colleagues (2001) noted: "Patients may be more responsive and less depressed at home, and our study revealed that all the patients were satisfied with home treatment and the ability to maintain a normal life." However, interviewees also note that some patients, especially those with elderly caregivers, may not feel capable of self-administering.

In making their choice, patients also consider their out-of-pocket costs. Patient obligations vary by site of care and coverage rules. For FFS Medicare beneficiaries, we heard multiple interpretations of coverage rules by discharge planners, home infusion providers, and home health agencies.

Role of discharge planners

Hospital discharge planners have the primary responsibility for coordinating services when a patient

requires a continued course of infused medication. As soon as the physician indicates that a patient will need continuing infusions postdischarge, the discharge planner begins to arrange care. She must determine, in coordination with the physician, whether the patient is a candidate for home infusion, the treatment regimen can be given safely in the home, the patient's health plan has a home infusion benefit, and the plan has a preferred home infusion provider. She may work with the physician to see if an effective treatment can be found that calls for only one or two administrations per day to simplify the home infusion process. Some interviewees told us that a majority of patients receiving IV antibiotics can be placed on a once per day regimen. Finally, she contacts a home infusion provider or home health agency that will take responsibility for the patient. After the patient's release, the discharge planner has no further contact with the patient.

Role of home infusion provider

Although home infusion providers obtain most of their referrals from hospital discharge planners, they also receive referrals from physicians and home health agencies. A home infusion pharmacy must be a state-licensed pharmacy that meets standards for a compounding pharmacy including maintenance of a clean room. When a home infusion provider accepts a patient, it must obtain authorization from a patient's health plan to provide services. Some home infusion providers we spoke to employed home infusion nurses. If providers do not have their own nurses, they make a referral to a home health agency for necessary nursing services. (With Medicare patients, home infusion providers also make referrals to home health agencies if the providers' nurses are not part of a Medicare-certified home health agency.)

Home infusion providers prepare drugs for home administration and deliver the drugs, needed supplies, and equipment. Providers generally must have the ability to respond to patient needs 24 hours a day, 7 days a week. They share responsibility for patient education with visiting nurses, including teaching the patient how to use the equipment to self-administer the drug, how to clean it, and how to recognize side effects that require immediate attention. Ideally, they begin patient education in the hospital before discharge. They are often the point of contact for patients, physicians, and health plans. If they coordinate care, they send blood work and other lab results to physicians on at least a weekly basis. Interviewees reported that on an initial visit home

infusion providers occasionally determine that patients are not capable of self-administration or that their homes are unsuitable.

While most health plans were satisfied with the services they received from contracted providers, a few expressed some concerns. One said that some companies simply drop off drugs without checking to ensure that someone is home to receive them. This practice presents a problem because many of these drugs require careful handling and refrigeration. Some physicians and health plans reported that providers differ in terms of the timeliness and reliability of their communication about patient conditions and lab results and tend to rely on providers who do the best job of communicating with the physician.

Role of the home health agency

Home health agencies receive referrals directly from discharge planners or from home infusion providers. The patient's health plan needs to authorize nursing visits. Interviewees noted that typically plans approve a standard number of visits based on diagnosis, although additional visits may be necessary if a patient has trouble self-administering or experiences adverse effects. Some plans authorize daily visits for elderly patients. The nurse must coordinate with the discharge planner and the home infusion provider to ensure that medication is delivered on time and that she is at the patient's home in time for the first scheduled infusion after discharge. Hospital discharge planners may not discharge a home infusion patient late in the day because it is not possible to arrange a nursing visit.

For antibiotics, the nurse typically visits twice during the first week of therapy to educate the patient and caregiver on how to use the equipment and to make sure they are able to do it. Typically, she visits once a week after the initial period. The nurse draws blood, monitors lines and catheters, and checks for medication errors. Some therapies require more nursing time. For example, several plans that cover IVIG at home require a nurse to be present at each infusion. In some cases, the nurse communicates lab results to the physician; in other cases, that is the responsibility of the home infusion provider.

The home health agency may provide services in addition to infusions for some patients. Wound care patients who need infusions also need services associated with wound care. Joint replacement patients receiving antibiotic infusions may also need physical therapy.

The nurse also provides continuing education. In some cases, a patient's medication is switched during the course of treatment because the prior drug was not working or the patient could not tolerate its side effects. The nurse is responsible for teaching the patient how and when to administer the new therapy.

Role of the health plan

Interviewees agreed that the goal of the health plan is to provide the least expensive, safest level of care. Oral drugs are preferable but are not always appropriate to treat the patient's condition. If home infusion is indicated, the health plan may have a preferred network of home infusion providers or home health agencies, and the hospital discharge planner refers the patient to one of them. Commercial plans generally cover home infusion under their medical benefit. The plan authorizes provision of home infusion, including the drug and number of nursing visits. If therapy is extended or changed, further authorization may be needed.

The plan's role in additional coordination of patient care varies, generally based upon health plan or delivery system integration. Integrated plans often have their own home infusion provider, home health agency, or both. A plan case manager coordinates services for the patient. Some integrated plans interviewed provide minimal home nursing care, preferring that patients come into their clinic once a week for monitoring if practical. In contrast, one integrated plan interviewed provides nursing for all home infusions, believing that it increases safety and is still more cost-effective than care in other settings. Interviewees from integrated systems also said that electronic health records played a crucial role in monitoring patient care, particularly as patients transitioned from the hospital to home.

Some plans actively encourage home infusion, reaching out to physicians and patients to let them know of its availability. Others more strictly limit circumstances in which home infusion is covered.

Plans that separate the pharmacy component from the medical benefit may do less patient coordination. One department monitors drug usage while another oversees coverage for medical care. This situation may create perverse incentives for overall cost and quality of care. For example, one interviewee reported that many health plans do not cover an expensive new oral antibiotic that can obviate the need for infusions. Within Medicare, a stand-alone drug plan may not find it advantageous to cover the

product while an integrated MA plan may consider overall costs of care lower with the oral drug.

Utilization management techniques

Health plans use a number of techniques to ensure that home infusion is being provided appropriately. Plans generally require prior authorization before home infusion therapy can begin. All plans that we interviewed reported using prior authorization techniques, although not for all drugs. Plans also conduct retrospective reviews after therapy has been provided.

- **Prior authorization**—Before home infusion therapy begins, plans must approve coverage. They generally ask physicians to report the diagnosis, prescribed drug, dosage, and expected duration of therapy. They may also request information about the patient's age, sex, and overall health status. Some plans require separate approval for a schedule of nursing visits. For Medicare patients, plans also determine whether the drug is covered under Part B or Part D and whether the patient has reached the Part D coverage gap.⁹ Physicians and providers told us that the prior authorization process is not burdensome and requests are approved quickly, although several reported that coverage overlap issues between Medicare Part B and Part D are administratively burdensome. One provider remarked that, unlike the uncertain outcome of postutilization review, prior authorization ensured that the agency would be paid for its services.

Some plans do not require prior authorization for every drug. Rules differ based on drug cost and appropriateness criteria. Plans that limit prior authorization to expensive drugs may not require it for most antibiotics. On the other hand, some plans worry that inappropriate use of antibiotics is leading to increased bacterial resistance to existing antibiotics, and they screen antibiotic use for appropriateness. Some check to make sure that oral medications have been tried first. Others, particularly plans in an integrated delivery system, may require an infectious disease specialist to consult and approve an antibiotic therapy order. The emphasis is on the appropriateness of the drug, not the site of care.

All plans we spoke with that cover IVIG in the home require prior authorization because of its high cost and its use for multiple off-label indications. Some plans do not consider IVIG safe for home infusion, although

others reported success with home use. One plan has a patient education program that teaches patients how to reduce use of IVIG. Additional drugs that some plans do not approve for home infusion include chemotherapy and infusions for rheumatoid arthritis.

- **Retrospective reviews**—All plans conduct retrospective reviews of home infusion therapy. The number and intensity of audits depend on the extent to which the plan emphasizes prior authorization. If prior authorization is limited, plans are more likely to rely on retrospective reviews. Auditors look for outliers, including excessive length of therapy and an abnormal number of nursing visits. For example, one physician noted that IV antibiotic therapy that lasts longer than eight weeks should “raise a red flag.” Plans also examine use of high-cost therapies like IVIG and clotting factor. Some plans look at differences in dosing for certain drugs and reach out to providers if they find unwarranted variation.

Ensuring safety and quality in home infusion

Plans generally contract with home infusion providers that meet certain standards. All home infusion pharmacies must be licensed under applicable state boards of pharmacy. Some providers mentioned that they were also accredited by the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Commission for Home Care.

A number of interviewees mentioned their efforts to develop quality metrics and track them. One provider participates in a quality tracking group with 300 other home infusion pharmacies to submit data on a number of quality indicators. This organization, Strategic Healthcare Programs, LLC, collects data on a number of quality indicators including unscheduled hospitalizations, central line infections, adverse drug events, incidents of acute renal failure, and frequent hospitalizations by patients receiving TPN. A representative of this organization told us that reporting is voluntary and organizations may use different definitions of concepts like adverse drug events. In fact, some providers may score worse on some measures than other providers because of a greater commitment to identifying adverse events rather than a greater prevalence of such events. She stressed the importance of a uniform assessment instrument to obtain consistent data across providers.

With some caveats, the research literature indicates that home infusion is a safe option for elderly patients. A

study in the Department of Veterans Affairs health system compared results from two cohorts of patients receiving home infusion: One group consisted of patients under age 60 years, the other group had patients age 60 or older. The study concluded that clinical outcomes and numbers of adverse events were similar in both groups, though the rate of nephrotoxicity was higher in the older group. Older patients also needed more support. They were “significantly more likely to require the assistance of family members to help with the infusion and were more likely to be seen in urgent care or to call the infectious diseases pharmacist or physicians with questions” (Cox et al. 2007).

Payment methodologies for home infusion

Interviewees indicated that most health plans provide a three-component payment for home infusion, but a few plans we spoke with pay with broader bundles or use a capitated approach. We did not independently verify information obtained from our interviews.

The three components of plans’ payments for home infusion consist of a payment for the drug; a per diem payment for supplies, equipment, pharmacy services, and other non-nursing services; and a payment for each nurse visit.

- **Drugs**—The majority of health plans interviewed paid for the drugs based on a discount off the AWP. Interviewees mentioned discounts ranging from 9.5 percent to 16 percent. A few health plans based their drug payments on a percentage of the wholesale acquisition cost or ASP.
- **Per diem for supplies, equipment, and other services**—Plans typically make a per diem payment to home infusion providers to cover supplies, equipment, pharmacy services, and other non-nursing services, such as administrative and care coordination services.¹⁰ The per diem rates vary depending on the drug being infused and the frequency of the infusion. In addition, the typical per diem payment for antibiotics varied across interviewees—ranging from \$75 to \$150. This range appeared to reflect variation in pricing across providers and insurers. Drugs that are provided intermittently (e.g., once per week or once per month) may receive a per treatment payment for supplies and other services instead of a per diem payment.

- **Nursing**—Most commercial plans pay for nursing on a per visit basis. A few interviewees provided estimates of the typical payment rate for a nurse visit, which ranged from \$80 to \$120.

While much less common than the three-component payment approach, some health plans make payments in broader bundles. For example, one large provider told us that some plans bundle nursing into the supply per diem, although this practice reportedly has become less common in recent years. One plan interviewed bundled the cost of certain relatively inexpensive antibiotics into the per diem for supplies. Another plan bundled nursing and supplies into the drug payment in some cases. Two plans interviewed used a capitated approach, making a per member per month payment to either a home infusion provider or a medical group to cover plan members' home infusion services.¹¹

The amount of cost sharing for home infusion varies by health plan. Plans and providers interviewed indicated that commercial plans normally have some cost sharing for home infusion but characterized it as typically not large. A few plans interviewed charge no cost sharing for home infusion, while some plans reportedly have very high member liability for home infusion.

Medicare beneficiary experience

Interviews of discharge planners, providers, and physicians provide insight into Medicare beneficiaries' experience accessing home infusion services, given the program's assortment of coverage rules under various benefits. According to the accounts of interviewees, beneficiaries' use of infusion services at home and in other settings varies regionally and across providers. This variation in part may reflect the multiple interpretations of Medicare coverage rules that we heard from discharge planners, home infusion providers, and home health agencies. For example, when Medicare covers only the drug, some discharge planners and providers told us that some providers offer beneficiaries lower prices or payment plans for supplies and equipment. Other providers told us that they were not allowed to do that. Interviewees also differed in their understanding of Part B coverage for supplies and equipment, with some believing that supplies and equipment coverage under the Part B DME benefit and Medicare home health benefit was more expansive than others.

For FFS beneficiaries, interviewees reported that out-of-pocket costs for home infusion are sometimes prohibitive and influence the site of care for some beneficiaries. We heard this statement for drugs covered by Part D and for IVIG covered by Part B. We generally did not hear concerns about out-of-pocket costs for home infusion drugs covered by the Part B DME benefit and prosthetic benefit, which also cover supplies and equipment. FFS beneficiaries with Medicaid coverage or employer-sponsored supplemental insurance that covers all components of home infusion generally have the easiest access to home infusion. For FFS beneficiaries without such coverage, discharge planners and providers gave varied accounts of the type and amount of out-of-pocket costs and the extent to which they lead beneficiaries to receive care at alternative sites.

- **Supplies and equipment**—Some discharge planners and providers indicated that the out-of-pocket cost for the per diem supply fee (typically \$75 to \$150 per day) made home infusion not an option for some beneficiaries. For example, a home infusion provider told us that its patients never pay out of pocket for home infusion because the per diem is cost prohibitive and they are not permitted to selectively discount. In contrast, other discharge planners indicated that out-of-pocket costs for supplies did not typically influence the site of care because some providers offer patients reduced prices, charity care, or payment plans, or they find other ways to provide the supplies if the patient does not have insurance coverage for the per diem payment. For example, one discharge planner told us that area providers would offer a per diem of \$30 to \$60 (depending on whether the drug was given once per day or multiple times per day) for beneficiaries with only Part D drug coverage and that most patients' families would pay that amount to avoid a nursing home stay.
- **Part D**—For those home infusion drugs not covered by Part B, interviewees indicated that Part D coverage was essential for access to home infusion. However, some providers and discharge planners told us that drugs prescribed were sometimes not on Part D plan formularies and that affected whether beneficiaries received home infusion. Discharge planners and providers also had varied perspectives on the Medicare Part D coverage gap. Some discharge planners indicated that the Part D coverage gap was the most significant out-of-pocket cost associated with home infusion and affected whether some beneficiaries

received home infusion, while other discharge planners said they rarely encountered issues with the coverage gap.

- **Nursing**—Except for IVIG, out-of-pocket costs associated with nursing services were rarely mentioned as a barrier to access for home infusion. With regard to antibiotics, most discharge planners indicated that patients who have been hospitalized in almost all cases meet the homebound requirement and can receive coverage for nursing through the Medicare home health benefit.

According to discharge planners and infectious disease physicians, some beneficiaries who would be candidates for home infusion of antibiotics receive infusions in SNFs and outpatient clinics (e.g., HOPDs and physician offices) because of the out-of-pocket costs associated with home infusion. The proportion of these beneficiaries going to SNFs versus outpatient clinics varied substantially across interviewees. Some interviewees told us that beneficiaries mostly went to SNFs if they faced out-of-pocket costs for home infusion that they could not afford. Others said it was more mixed, with some of these patients going to outpatient clinics and some going to SNFs. Still others said that beneficiaries would be unlikely to go to a SNF solely because of the financial costs of home infusion and would mostly receive infusions in outpatient clinics if home infusion was not a financial option. Whether these patients received care in SNFs or in outpatient clinics seemed to be influenced by a variety of factors related to the local health care market and the patient’s individual situation (e.g., travel time to outpatient clinics and hours of operation, infusion frequency, access to transportation and physical mobility, availability of SNF beds and willingness or unwillingness of SNF providers to admit patients needing infusions, complexity of the patient’s other medical needs, and patient and family preferences for outpatient care versus SNF care). A few discharge planners told us that occasionally a patient would stay in the hospital longer for infusions if alternative sites were not options.

Access to home infusion services also varies across MA plans, according to interviewees. Some told us that MA plans in their area provide home infusion coverage very similar to commercial plans, while others told us that MA plans’ coverage of home infusion was limited. A few interviewees noted that the Part D coverage gap can sometimes be a barrier to home infusion use by MA enrollees in plans that cover home infusion under Part D.

Potential for abuse of a Medicare home infusion benefit

We were asked to consider issues surrounding potential abuse of possibly broader home infusion coverage under Medicare. This issue is of interest because home infusion is at the crossroads of several areas of the Medicare program that have been vulnerable to fraud and abuse: home health, DME, and infusion drugs. In general, Medicare has had less ability to monitor care provided in the home than in facility settings and it has been more difficult to create payment systems with incentives for appropriate utilization.

Interviews with private health plans indicate that in their experience, fraud and abuse has not been more prevalent in the area of home infusion than in any other type of service. A few plans mentioned that contracting with a single home infusion provider helped facilitate oversight. In addition, plans’ utilization review activities—prior authorization and postpayment review—help deter and prevent abuse. One health plan described the need to look at home infusion utilization on a case-by-case basis to ensure it is appropriate and stated that in Medicare this kind of oversight would be complicated, as the separate entities administering the various benefits that included one or more home infusion components would need to coordinate their efforts. A physician interviewed thought that concerns about potential abuse if Medicare broadened coverage of home infusion were legitimate but that they could be addressed through utilization management, such as prior authorization. A few physicians mentioned utilization patterns that might be flags for possible abuse, such as IV antibiotics prescribed for conditions without supporting clinical evidence or antibiotic prescriptions exceeding six or eight weeks. While private payers have not found fraud to be a problem in the home infusion industry, a broad, unmanaged expansion of Medicare FFS coverage could lead to fraudulent actors entering the field.

One health plan interviewed reported encountering small issues with inappropriate billing for home infusion. According to the plan, some providers were double billing for drugs under the pharmacy benefit and the medical benefit, which the plan said was the result of a lack of understanding of the billing processes in some cases and purposeful in other cases. The plan put in edits to eliminate the issue. Some providers billed for more expensive prepackaged drugs when they actually furnished drugs made with ingredients from a bulk vial.

Our analysis of Medicare claims data and Part D prescription drug data found instances of unusual billing patterns that may merit further investigation and illustrate some of the potential vulnerabilities in Medicare. We found Part D claims for IV drugs dispensed while beneficiaries were in a Part A SNF stay. Drugs provided in a Part A SNF stay are covered under the Part A payment or are billable in some cases to Part B, not Part D. Thus, these Part D claims may represent double billing and merit further examination. A separate analysis of the Part B claims data found roughly 50 percent more beneficiaries receiving Part B–covered external infusion pumps than Part B–covered home infusion drugs. Part B covers pumps only to be used in conjunction with Part B–covered home infusion drugs, thus raising questions about the appropriateness of coverage for the pumps and warranting further scrutiny.

Assessment of cost data

The Congress requested that the Commission assess sources of data on the costs of home infusion therapy that might be used to construct payment mechanisms in the Medicare program. Data on the cost associated with providing home infusion services are limited. A study sponsored by the National Home Infusion Association that estimated the per diem costs of home infusion has methodologic limitations that reduce its utility for rate setting. Data on Medicare payment rates for similar services, such as home health and DME, might be a source of benchmarks. For example, the Medicare home health benefit has a payment rate for individual nurse visits (when four or fewer visits are provided in a home health episode). The DME fee schedule has payment rates for infusion pump rental and supplies, although the DME fee schedule is generally perceived to be above the costs of an efficient provider. Another avenue for obtaining cost information might be competitive bidding, as discussed later in this chapter. Also, the feasibility of obtaining data on providers' acquisition costs or manufacturers' sales prices for equipment and supplies could be explored.

The National Home Infusion Association sponsored a study conducted by Abt Associates to estimate the per diem costs associated with home infusion services (National Home Infusion Association 2006). The per diem was defined to include supplies, equipment and “all other services (e.g., referral processing, intake qualification and documentation setup, care coordination, verifying

physician order set, sterile compounding, packaging, delivery, patient education, clinical monitoring, insurance administration, etc.)” For the study, Abt obtained survey data from seven home infusion providers, five national companies, and two others. The home infusion providers submitted information on their aggregate per diem cost (combined for all types of patients, drugs, and frequencies of administration), share of patients by S-code (i.e., by drug and frequency of administration), supply costs by S-code, equipment costs by type of equipment, average salary and benefits by type of employee, and average delivery charges. Abt used this survey information, along with assumptions about the amount and type of labor and type of equipment involved with each S-code, to estimate per diem costs at the S-code level. The study reports average per diem costs by S-code based on its estimate of four components of cost: labor, supplies, equipment, and delivery. Costs for the four components are not reported separately. For antibiotics, the study reported an average per diem cost in 2004 ranging from \$70 to \$102, depending on the frequency of administration. For immunotherapy like IVIG, the study reported a cost per administration of \$554 in 2004, not including the cost of the drug and nurse visits.

Some aspects of the study limit its utility as a source of cost data for rate setting. The study estimates per diem costs using mostly aggregate cost data extrapolated to the S-code level based on assumptions about the amount of labor and type of equipment involved in each S-code. Ideally, cost information for rate setting would be more granular, such as actual data on the cost or amount of labor and type of equipment involved in each S-code. The per diem cost definition used in the study overlaps with some services covered through Medicare Part D (Table 6-2, p. 188). To avoid duplicate payment, any cost data that might be used to price expanded home infusion coverage should reflect only the expanded services to be covered, not services that are covered under another Medicare payment system. Some of the cost estimates in the study are at levels that raise questions about whether they are accurate and reflect efficient provision of care. For example, the study estimates a cost of \$554 per IVIG administration in 2004, not including the cost of the drug and nurse visits. Beyond the delivery and equipment pickup costs (estimated at \$38 each), the study does not break out the roughly \$500 in remaining costs. It is unclear to us what would explain costs at this level. Finally, the study is based on data from seven home infusion companies—ideally, cost information would come from a broader set of providers.

Part D dispensing fee (42 CFR 423.10)

Dispensing fees mean costs that (1) are incurred at the point of sale and pay for costs of a covered Part D drug each time a covered Part D drug is dispensed; (2) include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacy’s time in checking the computer for information about an individual’s coverage, performing quality assurance activities consistent with 42 CFR 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

NHIA definition of per diem

All other services (not including drugs and direct infusion nursing services)(e.g., referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, delivery, patient education, clinical monitoring, insurance administration), supplies, and equipment provided in conjunction with home infusion therapy.

Note: CFR (Code of Federal Regulations), NHIA (National Home Infusion Association).

Source: Code of Federal Regulations and National Home Infusion Association.

Cost implications of expanded home infusion coverage in Medicare

To examine the possibility that broader home infusion coverage under Medicare could save money by shortening or avoiding hospital or SNF stays, we conducted interviews with health plans, reviewed the relevant literature, developed a conceptual framework of the possible effects expanded home infusion coverage could have on Medicare expenditures, and constructed scenarios in which broader Medicare home infusion coverage may yield savings or additional expenditures compared with infusion in other settings.

Interviews

Health plans interviewed generally viewed home infusion as being cost-effective. Plans’ perceptions of cost-effectiveness were based on their sense of the relative payment rates; most plans had not conducted quantitative analyses to examine the comparative cost of infusions in the different settings. Compared with inpatient hospital and SNF settings, almost all plans indicated that home infusion was less expensive. One plan, which generally covers home infusion nurse visits only for homebound individuals (but makes medical exceptions), indicated that it is still evaluating whether home infusion is cost-effective compared with a SNF. Several plans also indicated that the

overall amount they paid for infusions in the home was less than the amount paid to HOPDs for infusions. A few also indicated that home infusion was less expensive than infusion in physician offices.

Some plans said they took cost-effectiveness into account when deciding whether to grant prior authorization. For example, some plans have a set number of nurse visits that they would expect for a particular drug regimen. If a home infusion provider requests more visits than the standard, the health plan may take into account the cost of the additional visits relative to the cost of receiving care in an alternative setting in deciding whether to approve the visits.

Caution must be exercised in extrapolating information on cost-effectiveness for private plans to Medicare. Medicare and private payers may have different payment structures or different relative payment levels across settings. For example, many private payers save money from shortened hospital stays because they pay hospitals on a per diem basis. Medicare makes a diagnosis related group (DRG) payment—that is, a fixed prospective payment—for a hospital stay and thus would not generally save as a result of a reduced hospital length of stay. Similarly, some plans interviewed indicated that their drug payment rates to HOPDs and physician offices were high relative to home infusion rates. In contrast, Commission analyses suggest that the rates paid for drugs by Part D plans

(which cover IV drugs in the home not covered under Part B) are generally higher than the rates paid by Medicare to physicians (ASP plus 6 percent) and by extension HOPDs (ASP plus 4 percent in 2012) (Medicare Payment Advisory Commission 2007).¹²

Literature on cost implications of home infusion

Though there is some literature on the costs of home infusion, most studies are old and do not estimate the costs of a home infusion program under Medicare's FFS payment systems. The key finding is that a day of home infusion therapy is less expensive on a per diem basis than a day of hospital or SNF care (Dalovisio et al. 2000, Nguyen 2010, Paladino and Poretz 2010, Poretz 1995, Tice 2000). One study pointed out that Medicare could end up making a "double payment" for patients discharged from the hospital with home infusion therapy (Medicare would pay the original DRG in addition to payments under a home infusion benefit) and suggested that Medicare would want to "reduce the possibility" of double payments if implementing a home infusion benefit (Poretz 1991).

Another study, conducted by infectious disease physicians, attempted to model the effect of a hypothetical new home infusion benefit on Medicare spending (Tice et al. 1998). The model assumed an unexpected increase in costs, or a "woodwork effect," resulting in increased use of the Medicare home infusion therapy benefit due to changes in prescribing behavior. The model also assumed a decrease in hospital admissions, expecting that some patients would be prescribed home infusion therapy in an outpatient setting rather than being admitted to a hospital. According to the study, the new benefit yielded Medicare savings, which were produced largely by eliminating hospital stays. The paper states, "if hospital admissions cannot be decreased to the level forecast in the model, Medicare savings will be significantly diminished." The model also includes a sensitivity analysis that shows—depending on assumptions about the extent of the woodwork effect, the per diem rate paid by Medicare, the number of avoided hospitalizations, and the hospital length of stay—a home infusion therapy benefit may lead to savings or increased costs for the Medicare program. This study predates changes in the Medicare payment system, such as the outpatient prospective payment system (PPS), the home health PPS, Medicare Part D, and Medicare's change in payment for Part B drugs from AWP to ASP, which lowered Part B drug spending substantially. Additionally, the study does not consider that costs would be shifted to

Medicare from other payers who currently pay for home infusion, such as Medicaid and employer supplemental insurance plans.

Conceptual framework

Whether expanded Medicare coverage for home infusion would save money or cost additional money depends on several factors related to drug type and setting shift, potential changes in prescribing patterns, and a potential crowd out of spending by other payers. To examine these factors, we developed a conceptual framework unifying a discussion of potential effects under three key questions.

1. To what extent would expanded home infusion coverage shift infusion services from non-home settings (e.g., hospitals, SNFs, HOPDs, physician offices) to the home and would such shifts increase or decrease Medicare expenditures?

The idea that home infusion coverage may generate cost savings is based on the premise that home infusion would substitute for care in more costly settings. Whether that is the case depends on whether patients shift from alternative sites to the home for infusion services and how Medicare payment rates for infusions in those alternative sites compare with payment rates that Medicare would establish for home infusion services.

If Medicare home infusion coverage were expanded, it is likely that some beneficiaries would shift from alternative settings to the home for infusions but we do not have data to determine how large a group of beneficiaries would make such a shift. Data are limited in two ways. First, the availability of data on the number of beneficiaries currently receiving infusions of a specific drug varies by setting. In settings where drugs are separately paid (physician offices and for drugs with a cost greater than \$75 per day in the HOPD), claims data are a good source of information on how many beneficiaries receive infusions of a particular drug in that setting. In settings where drugs are not separately payable, data are much more limited. For example, SNFs report administering an infusion drug through the Minimum Data Set but do not indicate the type of drug infused. Second, we would not expect all patients receiving infusions in a non-home setting to be candidates for home infusion and we do not have data to distinguish which beneficiaries would be capable of receiving infusions in the home.

Depending on the relative payment rates for infusions in the various settings, shifting beneficiaries from an

alternative setting to the home might increase or decrease Medicare expenditures for these beneficiaries. Table 6-3 shows the payment rates across non-home settings for drugs and drug administration in 2012. Settings vary in terms of whether drugs are paid separately or are included in the payment for another service. Whether a shift in site of care leads to an increase or decrease in expenditures depends on the effect on combined expenditures for the drug itself, any supplies and equipment, and administration services. The change in expenditures will depend on the payment rates Medicare establishes for home infusion services, the level at which cost sharing is set, and how that compares with payment rates and cost sharing in other settings. This calculus will also depend in part on the unit cost of the drug, the dosage, how frequently the drug is administered, and the length of time for each infusion. Consequently, cost implications may differ by drug and in some cases by drug and diagnosis (if dosage and administration frequency vary by diagnosis).

Possible savings from reduced SNF admissions for antibiotics—To the extent that some beneficiaries are candidates for home infusion but are admitted to SNFs for infusion services, opportunities likely exist to achieve savings on the costs of care for these beneficiaries by providing infusions in the home. Antibiotics seem to have the most potential for possible savings from reduced SNF admissions. A SNF stay must be preceded by a three-day hospital stay to be covered by Medicare. Consequently, SNFs are likely to be a potential site of care only for patients with acute illnesses needing time-limited infusion therapy, such as IV antibiotics for infections. For patients receiving IV drugs periodically for a chronic condition (e.g., IVIG or alpha-1 proteinase inhibitor), SNFs are unlikely to be a site of care for infusions and thus would not present an opportunity to shift care from nursing facilities to the home for these types of drugs. Medicare pays more than \$200 per day for care in SNFs for patients receiving infusions (\$223 to \$451 per day).¹³ Whether shifting a patient from a SNF to the home saves money on care for these beneficiaries depends on the cost of the drug (since drugs are separately payable in the home but are incorporated in the SNF prospective payment); Medicare payment rates for home infusion nursing, supplies, and equipment; and frequency of home nurse visits.

Significant savings from reduced length of hospital stay or reduced admissions are unlikely—Expanded coverage of home infusion may reduce hospital length of stay for some beneficiaries, but it is unlikely to yield

significant reductions in Medicare spending for most of these beneficiaries and it could lead to additional spending for some of them. Because Medicare makes a DRG payment for a hospital stay, Medicare payments to hospitals are unaffected by a shorter length of stay except in certain circumstances.¹⁴ Under the inpatient PPS post-acute care transfer policy, Medicare payment to a hospital is prorated on a per diem basis for certain DRGs when the length of stay is more than one day below the national average (geometric mean) length of stay for the DRG and the patient is transferred to a post-acute care site (e.g., SNF, home health care).^{15,16} For some hospitalized patients who need IV antibiotics, broader home infusion coverage might lead to shorter lengths of stay, but Medicare inpatient hospital spending would be reduced only to the extent that these beneficiaries are in DRGs covered by the post-acute care transfer policy and their use of home infusion shortens their length of stay to more than one day below the average length of stay for the DRG. However, length of stay may not fall enough to trigger reduced DRG payments, especially if patients who need a course of IV antibiotics tend to have medical issues of higher acuity than the typical patient within the DRG. For beneficiaries whose length of stay is reduced but not to this point or who are in DRGs not covered by the transfer policy, hospital payments would not change, while Medicare home infusion expenditures would increase. Shorter hospital stays could result in lower Medicare expenditures for physician services, as patients typically see a physician each day in the hospital. In some cases, the lower physician costs might offset the additional expenditures on home infusion; in other cases, Medicare expenditures would increase.

Some stakeholders have suggested that expanded home infusion coverage would reduce hospital admissions because some patients could be referred directly to home infusion rather than admitted to the hospital for infusions. While we do not have data on which to assess this potential, physicians and hospital discharge planners we interviewed told us that patients admitted to the hospital who receive IV antibiotics typically have serious medical issues that require a hospital level of care. Thus, we would not generally expect home infusion to substitute for hospital admissions. While some home infusion providers indicate that some privately insured patients who need IV antibiotics are directly admitted to home infusion without a hospital stay, we do not believe that necessarily implies that hospital stays would be averted if Medicare expanded home infusion coverage. It is not clear that patients

**TABLE
6-3**

Medicare payment rates for intravenous drug infusions across settings, 2012

	Inpatient hospital	SNF	HOPD	Physician office	Home health care
Drug	Packaged in DRG payment to hospital	Packaged in SNF PPS payment*	ASP+4%** for drugs with a cost per day greater than \$75 Packaged in the drug administration payment for drugs with a cost per day of \$75 or less	ASP+6%	Paid separately to pharmacy: 95% AWP if DME covered drug ASP+6% if IVIG for PID Part D negotiated rate for other drugs
Supplies and equipment	Packaged in DRG payment to hospital	Packaged in SNF PPS payment	Packaged in payment for administration	Packaged in payment for administration	Limited supply coverage for gravity infusions under home health benefit
Drug administration	Packaged in DRG payment to hospital Payment amount varies depending on patient diagnosis and is not affected by the provision of infusion drugs or in most cases by length of stay	Packaged in SNF PPS payment Per diem rate for relevant RUG groups: \$223.19 or \$261.74 per day (patient needing IV medication) \$281.02 per day (patient with foot ulcers) \$470.55 per day (patient requiring isolation)	\$126.64 first hour \$34.81 each additional hour	\$72.50 first hour \$21.44 each additional hour	Packaged in home health PPS payment \$2,808 for 60-day episode on average if 5+ visits \$112.88 per nurse visit if 4 or fewer visits
Cost sharing	Inpatient hospital deductible of \$1,156	None for days 1-20 and \$144.50 per day for days 21-100	20%	20%	None for home health Part D beneficiary cost sharing is actuarially equivalent to 25% but varies based on formulary tier; where the patient is relative to the deductible, standard benefit, coverage gap, and catastrophic limit; and whether the patient receives the low-income subsidy 20% for DME drugs and IVIG for PID

Note: SNF (skilled nursing facility), HOPD (hospital outpatient department), DRG (diagnosis related group), SNF PPS (skilled nursing facility prospective payment system), ASP (average sales price), DME (durable medical equipment), AWP (average wholesale price), IVIG (intravenous immune globulin), PID (primary immune deficiency), RUG (resource utilization group), IV (intravenous).

*While most drugs are packaged in the SNF PPS payment, certain chemotherapy drugs are paid separately.

**In the hospital outpatient prospective payment system, new drugs receive transitional pass-through status for two to three years during which time they are paid the average sales price plus 6 percent.

Source: MedPAC analysis of Medicare payment rates and cost sharing.

directly admitted to home infusion would have received care in a hospital rather than in an ambulatory setting absent coverage for home infusion. For example, one physician we interviewed indicated that patients directly admitted to home infusion tend to have less complex conditions, which may suggest they would otherwise be candidates for care in an ambulatory setting. With respect to immune-compromised patients, whether home infusion has the potential to reduce hospital admissions by reducing exposure to germs present in facilities is unknown. The literature has not compared infection rates among patients receiving infusions in the home versus other settings.

Shifting infusions from ambulatory clinics to the home may increase or decrease expenditures depending on relative payment rates—Whether home infusion would result in savings for patients currently receiving infusions in HOPDs and physician offices would depend on the payment rates that were established for home infusion supplies, equipment, and nursing. How would the rates compare with the drug administration payment rates in other ambulatory settings, and how much of a differential in drug payment rates exists across settings? Drug payment rates are slightly lower in HOPDs than in physician offices (ASP plus 4 percent in 2012 for HOPDs vs. ASP plus 6 percent for physician offices). Commission work at the beginning of the ASP system suggests that Part D drug payment rates are generally higher than ASP plus 6 percent, which would make drugs covered by Part D in the home higher cost than in the other settings (Medicare Payment Advisory Commission 2007). Differences in drug payment rates across Part B and Part D could influence whether overall Medicare saves or incurs additional costs from expanded coverage for home infusion, particularly for high-cost biologics for which modest percentage differences in payment rates can have a substantial impact in dollar terms. Drug administration payment rates are lower in physician offices than in HOPDs; however, these payment rates are not entirely comparable. The drug administration payment rate in HOPDs includes payment for low-cost drugs (with a cost of \$75 dollars per day or less) while such drugs receive a separate payment over and above the drug administration payment when administered in physician offices. Payment rates and cost-sharing amounts for home infusion services would have to be established and how those rates compare with payment rates in other settings would in large part determine whether home infusion generated savings or costs. It would also depend on the frequency of nurse visits. If a visiting nurse is needed periodically, a

possibility for savings may exist depending on the other factors discussed. In contrast, if a nurse is required for each drug administration in the home, shifting infusions from ambulatory settings to the home is likely to increase Medicare expenditures.

2. To what extent would broader coverage of home infusion services result in beneficiaries receiving IV medications in situations where they previously did not?

Often referred to as the woodwork effect, expanded coverage of home infusion may result in more beneficiaries receiving IV medications in situations where they previously received oral medications or other therapies. We do not anticipate this increase being driven by patient demand because IV drugs are not something that we generally expect patients to seek out.¹⁷ Also, prescribing an IV medication has inherent risks (e.g., bloodstream infections) and we do not expect physicians to take these prescribing decisions lightly. Nevertheless, to the extent that several different drugs are available for a specific condition, some IV and some oral (or other forms), and these drugs are perceived to have different clinical advantages, expanded coverage of home infusion would likely lead to more beneficiaries receiving IV medications. In general, more beneficiaries using IV medications would be expected to increase Medicare expenditures (except when an inexpensive IV drug substitutes for an expensive oral drug or other type of drug). The extent of the woodwork effect would likely vary by drug. Drugs with a narrow indication and precise diagnostic criteria (e.g., IVIG for PID) would be less subject to a woodwork effect than drugs with broad uses or less precise diagnostic criteria (e.g., antibiotics, as discussed later in this chapter). Also, to the extent that fraud occurs, it could be another factor contributing to increased use of IV drugs.

3. To what extent are beneficiaries currently receiving infusions in the home funded by other payers for which Medicare would assume responsibility under expanded coverage?

More than 100,000 Medicare beneficiaries receive home infusion drugs paid by Part D as of 2009. For these beneficiaries, expanding Medicare coverage for home infusion would represent additional costs, not savings, to the federal government through a crowd-out effect. Medicare would be assuming responsibility for services (e.g., supplies, equipment, and nursing) that otherwise would have been paid by other payers or by beneficiaries.

For dual-eligible beneficiaries, the amount of expenditures shifted to the federal government would be lessened by the fact that the federal government pays more than half of Medicaid expenditures.

For expanded home infusion coverage to realize savings for Medicare, any shifts in site of service would need to result in savings that exceed additional costs associated with crowd-out and woodwork effects.

Illustrative scenarios

The cost implications for Medicare of expanded home infusion vary by drug. As a result, a targeted expansion of home infusion coverage focusing on a subset of drugs would have more likelihood of savings than a broad expansion for all drugs. Factors that increase the possibility of savings are:

- if home infusion substitutes for SNF admissions;
- if home infusion substitutes for infusions in HOPDs or physician offices, nurse visits are needed periodically but not for each administration, and drugs are inexpensive or drug payment rate differences between Medicare Part B and Part D are small; and
- if some beneficiaries currently receive the Medicare home health benefit only because they need assistance with home infusion, then nursing might be provided less expensively through separately paid nurse visits for home infusion.

To explore the implications of broader coverage for home infusion, we developed illustrative scenarios of how the cost of infusions might vary across sectors for hypothetical patients for two products: antibiotics covered by Part D and IVIG covered by Part B for patients with PID. We chose these products (and diagnoses in the case of IVIG) because we believe they may offer a possibility, although not a certainty, of savings that would merit further exploration.

To create these scenarios, we made assumptions about how much Medicare would pay for supplies, equipment, and nursing if coverage for home infusion were expanded. The assumptions are meant to illustrate possible financial effects only and do not reflect an appropriate price or the best way to structure payments. For supplies and equipment, we assume that Medicare would pay a per diem amount for each day of an infusion, similar to the most common approach in the private sector. For potential payment rates, we assume three hypothetical per diem rates—\$30, \$60, and \$75—to

illustrate how different payment levels affect overall expenditures. The \$75 per diem is based on the lower end of the range that was typical for private payers we interviewed. The \$60 per diem is based on the current DME fee schedule rates for infusion pump rental and supplies. This amount may be an inflated benchmark, as DME fees generally are thought to be higher than the costs incurred by an efficient provider. The \$30 per diem is based on our interviews with discharge planners about the per diem rates offered by home infusion providers to their patients and reflects the low end of the range of those interviewed.

For simplicity, we assume Medicare would pay for each nurse visit on a FFS basis similar to the most common approach in the private sector. We assume a payment rate of \$113 per visit, based on the rate Medicare pays for individual nurse visits under the Medicare home health benefit when four or fewer visits are provided. While our example is based on a per visit payment methodology for nursing, this approach would create financial incentives for providers to furnish many visits and our example is not intended to imply that payment for nursing would be best structured in this way. To blunt these incentives, one approach that could be considered is to pay a per diem for nurse visits regardless of the number of visits provided. An alternative way to interpret our illustrative examples is that they indicate the amount Medicare would pay if nurse visits were paid on a per diem basis with the per diem rate set based on an assumption of an average number of visits per week. For example, the illustrative example for vancomycin could be interpreted as estimating Medicare payment if nurse visits were paid on a FFS basis and two visits per week were provided or if Medicare paid a per diem amount for nursing with the per diem rate established assuming an average of two visits per week. For patients who are homebound and need nursing care for needs beyond infusions (e.g., wound care), we assume all nursing is provided through the Medicare home health benefit at an average rate of \$2,808 per 60-day episode.¹⁸

Scenarios for antibiotics

Opportunities for savings might exist if Medicare expanded home infusion coverage to IV antibiotics for some beneficiaries. However, whether those savings would be large enough to offset the additional costs that expanded coverage would yield for other beneficiaries is unclear. We compared IV antibiotic infusion in the home with infusion in other settings:

- **SNFs**—For patients who need low-cost IV antibiotics like vancomycin, home infusion is likely to be substantially less expensive for Medicare than care in a SNF.¹⁹ How much could be saved from avoided SNF care depends on how many patients are admitted to SNFs who are candidates for infusions at home. Data are not available on this subject.
- **HOPDs**—Providing antibiotic infusions at home instead of in an HOPD may yield savings or additional costs depending on several factors. Home infusion is likely to increase Medicare expenditures compared with an HOPD if a nurse is required to be present at each administration. Alternatively, home infusion may cost less than infusions in an HOPD if nurse visits are needed periodically and those nurse visits are paid separately rather than through the home health benefit.
- **Home health care**—Some savings on home health expenditures may be possible for beneficiaries who currently receive infusion nursing through home health care if expanded home infusion coverage meant that nurse visits for infusions were paid for separately and beneficiaries avoided a home health episode. For beneficiaries who receive home health care for more than just infusion services, expanded home infusion coverage would likely increase Medicare costs because Medicare would now make additional payments for supplies and equipment above and beyond expenditures on the home health benefit.
- **Net savings or cost**—Overall, whether Medicare would save or incur additional costs from expanded coverage for home infusion of antibiotics is uncertain. It depends on whether providing infusions at home instead of in a SNF and possibly other settings yields savings that exceed the added costs Medicare would likely incur due to the crowd-out effect and the woodwork effect.

To examine costs, we developed the hypothetical example of a patient receiving 28 days of IV vancomycin administered once per day in different settings including at home (Table 6-4). Under various payment scenarios, we estimate Medicare payments for providing vancomycin infusions at home to be less than payments for infusions in a SNF or an HOPD. (Estimated payments in physician offices are also shown in Table 6-4, although very few beneficiaries receive vancomycin in physician offices.) The largest potential savings are for patients admitted to a SNF solely for infusions in the scenario

where they (or their family members) are trained to self-administer antibiotics at home and receive an average of two nurse visits per week. If such a patient received nursing through the Medicare home health benefit due to broader nursing needs beyond infusions, we estimate Medicare would still save relative to SNF care under our assumptions, although the savings would be smaller.

Under our assumptions, home infusion with two separately paid nurse visits per week is estimated to cost Medicare less than infusions provided through an HOPD. If we had assumed daily nurse visits instead of two nurse visits per week, Medicare payments for home infusion would have been higher than payments for infusions in an HOPD under a \$60 or \$75 per diem rate.^{20,21} Home infusion with nursing provided through the Medicare home health benefit is estimated to cost more than infusions in an HOPD.²² If infusions are needed more than once per day and home nurse visits are needed periodically, home infusion (regardless of whether the beneficiary receives the Medicare home health benefit) is estimated to be less expensive than infusions in an HOPD (not shown in Table 6-4).²³

Table 6-4 also helps illustrate the additional Medicare expenditures that would result from Medicare assuming responsibility for services whose costs otherwise would have been borne by supplemental insurers, Medicaid, or beneficiaries. In 2009, more than 56,000 beneficiaries received IV antibiotics paid for by Part D. Most received Medicare home health simultaneously. In our hypothetical example, expanding Medicare coverage to include equipment and supplies for a beneficiary who receives nursing through home health care would increase Medicare expenditures by at least \$672 (\$3,751 minus \$3,079). However, savings could accrue for a subset of beneficiaries currently receiving nursing for IV antibiotics through the home health benefit if expanded home infusion coverage meant they would no longer receive home health services and instead would receive separately paid nurse visits for infusions. In our hypothetical example, we estimate current spending for home health care at \$3,079 and spending for home infusion with separately paid nurse visits between \$1,666 and \$2,674. For beneficiaries receiving Part D–covered IV vancomycin at home but not through the Medicare home health benefit, Medicare expenditures in our hypothetical example are estimated to increase by at least \$1,395 (\$1,666 minus \$271) if Medicare-expanded coverage included supplies, equipment, and nursing.

**TABLE
6-4**

Hypothetical example of Medicare payments for vancomycin for a patient receiving four weeks of once daily infusions

	Home					
	SNF	HOPD	Physician office	Current policy	3 scenarios for Medicare coverage of:	
Supplies, equipment, and nursing at hypothetical rates					Supplies and equipment at hypothetical rates and nursing through the home health benefit	
Drug	Packaged	Packaged	\$10.73 per day	\$12.89 per day	\$12.89 per day	\$12.89 per day
Supplies and equipment	Packaged	Packaged	Packaged	\$0	(i) \$30* per day (ii) \$60* per day (iii) \$75* per day	(i) \$30* per day (ii) \$60* per day (iii) \$75* per day
Drug administration	Packaged in SNF per diem \$223.19–\$470.55 per day	\$161.45 per administration	\$93.94 per administration	\$0 or \$2,808 if home health benefit	\$113* per visit (assume 2 visits/week)	\$2,808 per 60-day home health episode
Payment, 28 days, 1 administration per day	\$6,249–\$13,175	\$4,521	\$2,931	\$361 or \$3,169 if home health benefit	(i) \$2,105* (ii) \$2,945* (iii) \$3,365*	(i) \$4,009* (ii) \$4,849* (iii) \$5,269*
Medicare payments net of cost sharing	\$5,093–\$12,019	\$3,616	\$2,345	\$271 or \$3,079 if home health benefit	(i) \$1,666* (ii) \$2,338* (iii) \$2,674*	(i) \$3,751* (ii) \$4,423* (iii) \$4,759*

Note: SNF (skilled nursing facility), HOPD (hospital outpatient department). Estimates assume a patient receiving intravenous vancomycin for 28 days, 30 milligrams per kilogram (weight 70 kilograms), once per day. Cost sharing is assumed to be 25 percent for Part D drugs and 20 percent for home infusion equipment, supplies, and separately payable nurse visits. Cost sharing for physician office and outpatient services is 20 percent, for SNF services is \$144.50 per day for days 21–28, and for the Medicare home health benefit is zero. Average Part D payment rate is not net of rebates, if any.
*Based on hypothetical payment rates for illustrative purposes.

Source: MedPAC analysis of Medicare fee schedules, and Part D data from Acumen, LLC.

We would also expect increased expenditures because of a woodwork effect. That is, we anticipate more Medicare patients would receive IV antibiotics than otherwise would be the case because of expanded coverage of home infusion. As noted previously, a study by infectious disease physicians that modeled the financial impact of expanded home infusion coverage for antibiotics assumed a woodwork effect to account for changes in prescribing patterns (Tice et al. 1998). Antibiotics may be particularly susceptible to a woodwork effect because research suggests they are sometimes prescribed

by physicians without appropriate clinical indications. Analyses of antibiotic use have consistently shown that inappropriate use of antibiotics is a contributing factor to growing microbial resistance to antibiotics (Avorn and Solomon 2000, Cadieux et al. 2007, Colgan and Powers 2001). One meta-analysis of methods to improve antibiotic prescribing practices in hospitals noted that as much as one-half of antibiotic use in hospitals is inappropriate (e.g., used to treat viral infections) (Davey et al. 2009). As noted previously, one study specifically looking at prescribing patterns for IV antibiotics in one hospital

found that 27 percent of the time they were prescribed inappropriately when antibiotics were not indicated, when an equally effective oral product was available, or for other reasons. We also heard similar concerns from some interviewees. For example, one infectious disease specialist noted that he comes across cases in which infused antibiotics are prescribed for patients with infected devices or joint replacements. Unless the infected device is removed, antibiotics cannot fight the infection. One health plan reported that the plan always requires prior authorization for infused antibiotics even if the drugs are inexpensive. The goal is to prevent inappropriate antibiotic use leading to further development of drug-resistant bacteria. Given this fact, we would expect expanded coverage of home infusion for antibiotics to increase prescriptions for IV antibiotics, and that would increase program costs. Overall, whether Medicare costs increase or decrease with expanded home infusion coverage depends on the relative size of all the dynamics discussed. To make this determination, we need certain data that are currently lacking. We lack data on the number of beneficiaries who would shift from alternative settings to the home under broader coverage of home infusion and the amount of increased utilization that would occur due to a woodwork effect. Another source of uncertainty is that the amount of savings or additional costs that would occur for beneficiaries who shift to the home depends on many factors, including the payment rates that would be established for home infusion.

It may be possible to collect additional data to fill in some of the information gaps, although at least one gap would be very difficult to fill. We do not know how many beneficiaries in SNFs receive IV antibiotics, which antibiotics, and for how long. Potentially, SNFs could be required to report more detailed data on antibiotic infusions on claims or the Minimum Data Set. A second gap concerns how many patients currently receiving infusions in non-home settings would be candidates for home infusion. A survey of hospital discharge planners, who are likely best positioned to know placement options for patients, could be considered. Such a survey would need to be nationally representative and would likely be expensive. We also lack data to estimate the size of the woodwork effect and it is unlikely that data could be collected to predict what changes in prescribing patterns would occur under broader coverage.

IVIG for primary immune deficiency

In another hypothetical example, we examined the possible effects of expanded coverage for nursing,

supplies, and equipment for patients receiving IVIG for PID in the home. While uncertain, our hypothetical example suggests savings might exist from expanded coverage for home infusion for the PID population because of potential substitution of IVIG for subcutaneous immune globulin. Currently, for beneficiaries with PID, Medicare covers IVIG in the home under Part B but does not cover supplies, equipment, and nursing. Interviewees told us that IVIG must be administered by a trained medical professional. A substitute product—subcutaneous immune globulin—is covered in the home, along with supplies and equipment, through the DME benefit. Nursing is not covered for subcutaneous immune globulin because it is considered self-administered. As of 2009, we estimate that about 2,000 beneficiaries with PID received immune globulin at home; two-thirds of them received the subcutaneous product and one-third received IVIG. This pattern of use differs from that in the private sector, where IVIG is reportedly more common than subcutaneous immune globulin in the home according to interviewees. As shown in Table 6-5, the subcutaneous product is much more expensive than IVIG. If beneficiaries shifted from using subcutaneous immune globulin to IVIG, savings to Medicare for those beneficiaries would be sizable (at least \$882 per patient per 4-week period in our hypothetical example). The subcutaneous product is very expensive for two reasons: Medicare pays for subcutaneous immune globulin at 95 percent of AWP (the policy for drugs covered under the DME benefit), and the labeled dosage of the subcutaneous product is 37 percent to 53 percent higher than the IVIG dosage.

Our hypothetical example also shows that there would be increased costs for some beneficiaries if Medicare expanded coverage for home infusion services for patients with PID receiving IVIG. Home infusion is estimated to be more expensive for Medicare (i.e., additional cost ranging from just under \$20 to \$75 per patient per 4-week period) than infusions in HOPDs and physician offices. Also, for those beneficiaries currently receiving IVIG at home, if Medicare expanded coverage to include supplies and equipment, we estimate Medicare program expenditures would increase by at least \$114 per patient per 4-week period (\$1,785–\$1,671) due to the crowd-out effect. We anticipate that the woodwork effect would be minimal in the case of IVIG for PID. Physicians we spoke to indicate that the laboratory criteria for diagnosing PID are very specific and IVIG is the only treatment option for most patients diagnosed with PID.²⁴ Overall, whether expanded coverage of home infusion services for patients

**TABLE
6-5**

Hypothetical example of Medicare payments for immune globulin across settings for patient with primary immune deficiency per four-week period

					IVIG at home
	IVIG HOPD	IVIG physician office	Subcutaneous IG home	Current policy	3 illustrative scenarios if Medicare covered supplies, equipment, and nursing at hypothetical rates
Drug	\$2,049	\$2,088	\$3,304–\$5,055	\$2,088	\$2,088
Supplies and equipment	Packaged	Packaged	\$29	\$0	(i) \$30* (ii) \$60* (iii) \$75*
Drug administration	\$161	\$94	Not applicable	\$0	\$113* per visit (assume visit for each administration)
Total payment for a four-week period	\$2,210	\$2,182	\$3,333–\$5,084	\$2,088	(i) \$2,231* (ii) \$2,261* (iii) \$2,276*
Medicare payments net of cost sharing	\$1,768	\$1,746	\$2,667– \$4,068	\$1,671	(i) \$1,785* (ii) \$1,809* (iii) \$1,821*

Note: IVIG (intravenous immune globulin), IG (immune globulin), HOPD (hospital outpatient department). For IVIG, estimates assume 28 grams administered for 2 hours once every 4 weeks (based on a dosage of 400 milligrams/kilogram for person with weight of 70 kilograms). For subcutaneous IG, estimates assume a dose ranging from 100 percent to 153 percent of the IVIG 4-week dose divided by 4 and administered weekly. Payment rates reflect the first quarter of 2012. For drug payment rates, the median payment rate across available drug products is used. For the hospital outpatient department, we assume IVIG is paid average sales price plus 4 percent. *Based on hypothetical payment rates for illustrative purposes.

Source: MedPAC analysis.

with PID who use IVIG would increase or decrease Medicare program expenditures depends on whether the savings from patients shifting from subcutaneous immune globulin to IVIG would be enough to outweigh additional costs from patients potentially shifting from HOPDs and physician offices to home and from the crowd-out effect. Similar to the antibiotics example, we are unable to draw a conclusion about the potential net effect on Medicare expenditures because of a lack of data (e.g., we lack data on the share of beneficiaries with PID who would shift from subcutaneous immune globulin to IVIG and from infusions in ambulatory settings to the home).

Design considerations for expanded home infusion coverage in Medicare

Although Medicare beneficiaries have access to infusion therapy at multiple sites of care, they may have more

difficulty receiving infusion therapy at home than privately insured individuals. Coverage gaps in FFS Medicare result from the way coverage is divided between Part A and Part B benefits and among separate payment systems, each with its own benefit design and coverage rules.

We examined two approaches for increasing access to home infusion: filling in the gaps in current coverage and setting up a demonstration project to test the effects of providing an integrated home infusion benefit for beneficiaries needing infused antibiotics. Each approach has advantages and drawbacks. We examined the gap-filling approach by considering policies for IVIG under Part B and antibiotics under Part D. We examined the integrated benefit approach through a project that would test quality and efficiency under an integrated home infusion benefit for antibiotics. The project could also test the ability of CMS to administer a targeted prior authorization policy.

Filling in the gaps

Medicare home infusion coverage is determined by the required medication, necessary equipment, and patient diagnosis. Coverage gaps exist for some of the elements needed to access home infusion, including supplies, equipment, and nursing. If the Congress wished to expand coverage for home infusion, it could fill in coverage gaps that prevent some beneficiaries from accessing home infusion therapy. Such changes could be incremental and limited or broader in scope.

A single policy may be inappropriate to cover all home infusions. Some products are more dangerous to infuse at home, require multiple daily infusions, or are provided as chronic periodic infusions. We focused our review on policies related to two products—immune globulin and antibiotics—as immune globulin accounts for a small number of users but entails a high cost per user and is covered under both Part B and Part D, whereas IV antibiotics covered under Part D account for the largest number of users of Medicare-covered home infusion drugs.

Coverage expansion for IVIG

Individuals with PID need immune globulin periodically on an ongoing basis. It can be provided intravenously (IVIG) or subcutaneously. By statute, beneficiaries with this diagnosis can receive IVIG under Part B at home. However, nursing and other supplies and services needed for this therapy are not covered. In general, a nurse must infuse IVIG directly into the patient's vein during each administration. Without access to nursing services, beneficiaries may be unable to use the home infusion benefit.

Beneficiaries sometimes substitute subcutaneous immune globulin for IVIG and self-administer. The pump needed to administer the therapy is covered by Medicare. However, this method is not appropriate for all patients. It is also more expensive as IVIG is paid at a rate of ASP plus 6 percent under Part B and subcutaneous immune globulin is paid at 95 percent of AWP under the DME benefit, a considerably higher rate. CMS has declined to include infusion drugs under its DME competitive bidding program. Further, subcutaneous administration currently requires more immune globulin per treatment.

Filling the gap in coverage for home infusion of IVIG for patients with PID could have the following advantages:

- It would apply to a small number of beneficiaries and its costs could be measured relative to beneficiaries

receiving IVIG in other settings or subcutaneous immune globulin.

- Some physicians told us that home infusion is the safest setting for individuals with compromised immune systems. Others said it was more a matter of convenience. Studies on this issue are lacking.
- It could reduce the use of immune globulin as fewer beneficiaries would need to receive the product subcutaneously.

Potential disadvantages exist, namely:

- Adverse events can result from infusions of IVIG and therefore it must be administered by a trained nurse. There may be fewer resources in the home to treat complications. Some private plans do not cover IVIG at home because of concern about wastage of the product if it is not handled properly. (Other plans provide home coverage and think it is a more efficient method.)
- If rates for nursing services, supplies, and equipment were set too high or if more nursing hours were needed than anticipated, the coverage expansion would increase costs.

Coverage expansion for IV antibiotics

Gap filling could also apply to IV antibiotics, covering the broadest proportion of beneficiary infusion users. The drugs, mostly inexpensive, are covered under Part D but Medicare does not cover any of the supplies and equipment needed for this infusion. To self-infuse antibiotics, beneficiaries need an infusion set and other supplies required for the gravity method of infusion or disposable pumps. They also need someone to teach them how to infuse and check on their progress periodically, including the results of lab tests. Nursing services are also not covered under Part D.

If the Congress wished to expand home infusion coverage for antibiotics, Medicare could provide coverage for the necessary supplies, equipment, and services. Generally, the gaps are twofold: coverage for supplies and equipment and coverage for other services frequently paid by private payers as a per diem amount, including lab monitoring and care coordination. Our data indicate that most beneficiaries receiving IV antibiotics under Part D are also receiving home health benefits including skilled nursing services. The home health benefit includes limited coverage of infusion supplies for infusions using the gravity method.

However, CMS guidance is not specific, and it is not clear that all required supplies and equipment are covered. CMS could clarify explicitly what is and is not covered, and if there are gaps, coverage could be expanded to the supplies (and possibly equipment) covered under the home health benefit.

Beneficiaries who are not homebound can receive lab tests, catheter and line care, education, and monitoring services through their physician's office. Several integrated plans that we interviewed preferred this method to coordinate patient care. One infectious disease specialist that we spoke to said it was the best way to ensure quality care. Patients come weekly to his office where the staff provides all necessary services. No home-based nursing is required.

There is some ambiguity about the extent to which other services needed for home infusion are covered through Part D (see Table 6-2, p. 188). CMS guidance states that the dispensing fee for covered Part D drugs includes any reasonable costs associated with a pharmacy's costs for checking information about an individual's coverage, performing quality assurance activities, measuring or mixing of the covered drug, filling the container, delivery, special packaging, and overhead associated with maintaining the pharmacy. These activities are included in the National Home Infusion Association definition of services covered through the per diem they usually receive from private payers.

A second gap relates to Medicare's payment for dispensing fees. Some home infusion providers we interviewed told us that the dispensing fees paid by Part D plans did not cover their costs for drug delivery and other aspects of pharmacy dispensing and indicated that they agreed to participate in Part D networks only because beneficiaries with Medicaid and some employer supplements had additional coverage for supplies, equipment, and other services. Beneficiaries without this additional coverage may not be able to obtain home infusion drugs from pharmacies in their Part D plans. We are unable to determine whether the dispensing fees that Part D plans negotiate with home infusion pharmacies are high enough to cover the services listed as required under the Part D guidance. On average, our data show that infusion pharmacies are paid about \$4 per drug, similar to the dispensing fee paid to retail pharmacies. Although CMS cannot require plans to negotiate dispensing fees that reflect the costs of providing mandated services, it can require plans to have adequate home infusion pharmacy networks that provide these required services without

additional payments. Such a requirement would not include the costs of supplies, equipment, and ongoing lab monitoring.

There are several advantages to such a requirement:

- Coverage for these services is already required under Part D.
- Ensuring coverage for these services through Part D may be the most efficient coverage method because it builds on tools such as prior authorization that plans already have in place to manage infusion drugs.

Disadvantages to this requirement:

- Plan bids could rise for all beneficiaries to account for the extra cost of providing these services, although the number of beneficiaries receiving home infusion is comparatively small.
- This approach would not fill the gap in coverage for supplies and equipment.

A third coverage gap relates to necessary home infusion supplies and equipment that are not covered under the DME fee schedule. Supplies needed to use the gravity method and disposable pumps are not covered under DME and it is unclear to what extent they are covered for home health recipients. The Congress could extend the DME fee schedule to cover these supplies and equipment, including tubing, disposable pumps (specifically for home infusion of antibiotics), and infusion poles.

There are two advantages to covering supplies and equipment:

- Physicians told us that home infusion is the standard of care for infused antibiotics, although it is not appropriate for all patients. Some beneficiaries, particularly those not homebound, would have greater access if supplies were covered.
- Because the coverage of infusion supplies and equipment would foster greater use of the home setting, Medicare might be able to realize cost savings from those beneficiaries who otherwise would have been admitted to SNFs only for the purpose of receiving infusion therapy.

This approach has several potential disadvantages:

- Discussions among policymakers and the industry suggest that prices under the DME fee schedule

are not accurate. DME has been transitioning to a competitive bidding system but infusion drugs and associated equipment and supplies have not been included in the program up to this point.²⁵ Would policymakers want to increase the number of items paid for under a currently flawed payment system?

- Because DME has been implicated in a disproportionately large number of fraud cases, policymakers could be reluctant to increase the number of products covered through the benefit.
- It could be hard to ensure that all beneficiaries receiving these products required home infusion, as utilization management is difficult under a FFS payment system. There is greater potential for a woodwork effect in which individuals who could be taking oral drugs instead receive infusion therapy or receive infusion therapy for longer periods of time than appropriate in the absence of effective management of the benefit.

Home infusion antibiotic therapy demonstration

In its study of home infusion therapy, GAO recommended that the Secretary of Health and Human Services conduct a study of the advantages and disadvantages of including a comprehensive home infusion benefit under Medicare (Government Accountability Office 2010). Given the lack of data to analyze this issue, CMS could design a project under the Innovation Center to test the quality and efficiency of providing an integrated home infusion benefit for antibiotics. An integrated benefit has the potential to better coordinate patient care.

Such a project, if it could be properly designed, would allow an evaluation of whether a home infusion benefit improves quality and saves money compared with the current options beneficiaries face. The project would have to take into account the effects of crowding out current payers (e.g., retiree benefits) and the woodwork effect. It might also test multiple models to determine the most efficient way to deliver the benefit. Designing such a demonstration would require addressing several challenges.

The project would need management controls, including prior authorization, to ensure that antibiotics are being used properly. Plans we interviewed included prior authorization for some or all drugs used in home infusion. Physicians we interviewed did not find current plan prior authorization protocols overly burdensome or

time-consuming. This management tool is most easily implemented in an MA plan and some MA plans already include an integrated home infusion benefit. Since the plans take financial risk for all their enrollees' medical costs, they have the incentive to account for the woodwork effect in their benefit design. Plans have the authority to provide an integrated home infusion benefit under current law and are not candidates for a demonstration project.

A project testing provision of a home infusion therapy benefit would have the added advantage of testing Medicare's ability to implement a targeted prior authorization program. Implementing management controls within FFS Medicare poses a challenge. CMS or its contractor could provide oversight but, given its limited resources, CMS will be challenged to implement prior authorization and other management tools. Although private plans have well-developed algorithms to determine appropriateness under prior authorization programs, these algorithms are proprietary so the agency would need to develop its own tools. By developing and publishing prior authorization policies according to evidence-based guidelines, the agency could improve the transparency of the process for beneficiaries and providers. Additionally, prior authorization can be labor intensive and require considerable resources. For CMS, savings resulting from management would accrue to the Medicare program but management costs would come from its administrative budget. However, targeted prior authorization could be a useful tool to control inappropriate utilization not just in home infusion but in other areas as well. If CMS is able to administer a targeted prior authorization program, benefits would accrue to the program as a whole.

Home infusion therapy could also be implemented through an accountable care organization, which might be appropriate to manage home infusion therapy, as it assumes broad accountability for care and expenditures for its patients. Whether accountable care organizations would be interested in participating in this type of project is uncertain, given that home infusion of IV antibiotics would likely be relevant to a small share of their patients. If accountable care organizations were interested in participating, details would have to be worked out on how they would be paid for home infusion services and how payment would factor into the shared savings calculations.

One of the biggest challenges to a project under the Innovation Center would be determining an appropriate control group. One option might be to select demonstration areas. An independent evaluator

could identify diagnoses that are associated with the use of IV antibiotics and measure Medicare payments for all beneficiaries in the area with these diagnoses. The evaluator could then compare these payments with Medicare payments in similar areas outside the project for beneficiaries with the same diagnoses. It could also look at changes in spending for the selected diagnoses over time in the project and control areas. Although not perfect, this design would take into account shifts in costs to Medicare, the woodwork effect, and the fact that not all beneficiaries who need antibiotic infusion therapy are candidates for home infusion. However, it may be difficult to disentangle the effect of the project from unrelated effects if IV infusions are a low-frequency event for beneficiaries with the selected diagnoses or infusion-related costs account for a small share of their overall expenditures. Focusing on episodes of care and expenditures and service use by type of service might help isolate the effects. The evaluator would have to address additional methodologic challenges as well.

Participants would have to report quality measures to ensure that beneficiaries are receiving appropriate care. Some home infusion providers told us that they report quality measures to a benchmarking group, while others depend on pharmacy certification standards in their state. CMS, perhaps with the help of the National Committee for Quality Assurance, would have to develop a set of measures to determine the quality of care participating beneficiaries receive. Measures could include adverse events, hospital readmissions for infections including catheter and line infections, and postutilization reviews of the appropriateness of the therapy. CMS or its contractor would also have to survey beneficiaries to determine their satisfaction with their care.

Some fundamental design issues would need to be addressed:

- **Who would participate in the project?** As we have discussed, home infusion requires coordination. Any project participant would have to coordinate among multiple providers—including physicians, home infusion providers, home health nurses, and hospital discharge planners—and some applicants might propose partnerships among eligible providers. Physicians with expertise in infectious diseases might take the lead in the demonstration, as they have the most expertise in determining which patients need infused antibiotics and which therapies are most appropriate. Alternatively, home infusion providers
- **What would the payment cover?** Payment could cover supplies and equipment, needed services including nursing, and drugs. If the payment included the cost of drugs, participants would have to coordinate with the beneficiary's Part D plan, which would be responsible for the beneficiary's other medications. Similarly, the relationship between the project participant and any home health agency providing additional care (e.g., wound care) would have to be determined.
- **How would payment be set?** Similar to the private market's payment method for home infusion therapy, Medicare could make a separate payment for drugs, nursing, and a per diem payment for supplies, equipment, and services. Medicare could also bundle payment as part of an episode of care or bundle nursing along with supplies and equipment as part of a per diem amount. Alternatively, Medicare could use competitive bidding by project applicants to determine payment rates. As with other competitive bidding demonstrations, the payment could be set by the average bid of successful applicants, or demonstration participants could be paid their bid. Depending on how the project is designed, Medicare could pay a capitated rate for supplies, equipment, nursing, and other services if accountable care organizations participated in the demonstration.
- **How would beneficiary out-of-pocket costs be determined?** Beneficiaries pay an average of 25 percent coinsurance during the initial coverage period for Part D drugs, although cost sharing varies by drug and plan and the benefit phase the beneficiary is in at the time of dispensing. Beneficiaries whose drug costs are above the catastrophic threshold face lower cost sharing. Under traditional Medicare, beneficiaries pay no cost sharing for the home health benefit and 20 percent for covered DME. CMS would have to determine appropriate cost sharing for a project.
- **How would the population eligible for the project be selected?** Policymakers would have to define the patient population eligible to take part in the project. A participant might propose a service area to provide

home infusion services. FFS beneficiaries within that area would have the opportunity to participate in the project or continue current options if they needed infusion therapy. Patients without alternative sources of coverage would be likely to participate in the demonstration.²⁶ Alternatively, a project approved under CMS's Innovation Center could allow an accountable care organization or other integrated delivery system to test an integrated home infusion benefit for its members.

- **Would the drug be included in the payment? If so, what would the payment rate be?** Currently, infused antibiotics are covered under Part D. Each drug plan negotiates its own price with manufacturers and home infusion pharmacies. The plan receives a capitated payment from Medicare and enrollees to cover all Part D drugs, including home infusion drugs. If the drugs are removed from Part D, participants may have to negotiate their own drug prices, an area in which some may not have expertise. Payment to Part D plans might also have to be adjusted. Also, beneficiaries with high out-of-pocket costs might not have the benefit of the Part D out-of-pocket cap. If the infusion drugs remained in Part D, project participants would have to abide by the formularies and management tools of their enrollees' plans. These requirements could conflict with the project participant's decisions about the best treatment for a patient.

Coordinated home infusion therapy is most applicable within a managed care environment. However, despite the many challenges of testing an integrated home infusion antibiotic project in FFS, the Medicare program and its beneficiaries could benefit if a well-designed project allows policymakers to determine whether increased beneficiary access to home infusion for antibiotics improves quality and saves money compared with the current situation. Testing the ability of CMS to implement a targeted prior authorization program could have broader utility.

If an antibiotic demonstration results in improved quality and lower costs, Medicare might consider extending the project to other products, but caution would be essential. Each product requires different supplies, equipment, and nursing services. Thus, potential costs or savings would differ. Although the most likely source of savings with home infusion of antibiotics would be avoided SNF stays, SNFs are not an alternative for many other kinds of

infused therapies. Additionally, multiple studies have been done of home infusion for antibiotics, while less is known about trade-offs for other therapies using home infusion compared with other sites of care. The potential for a greater woodwork effect, leading to inappropriate use of home infusion therapy, would have to be evaluated.

Administrative issues

In the course of our study, we found a number of instances in which CMS coverage policies and guidance are subject to conflicting interpretations. For example, when Medicare covers only the drug, some discharge planners and providers told us that some providers offer beneficiaries lower prices or payment plans for supplies and equipment while others said that they were not allowed to do so. Interviewees also differed in their understanding of Part B coverage for supplies and equipment, with some believing that coverage for supplies and equipment under the Part B DME benefit and Medicare home health benefit was more expansive than others. CMS should consider the need to clarify coverage policies for home infusion as well as other services to ensure that the program is administered consistently across the country. Additionally, CMS can require Part D plans to have adequate home infusion pharmacy networks that provide all required dispensing and delivery services (excluding supplies, equipment, and nursing) without additional payment.

Conclusion

A lack of data impairs our ability to determine whether net savings would result from broader home infusion coverage, even in the case of a targeted expansion (e.g., antibiotics, or IVIG for PID). Although it is unsatisfactory to be unable to draw a conclusion about net savings or costs, collection of additional data might be possible to fill in some of the data gaps, but it would be difficult to collect all the data needed. Given the lack of necessary cost and utilization data, the Commission has not made any recommendations.

The specific questions the Congress asked the Commission to examine and the study's findings concerning these issues are:

- 1. An assessment of the literature relating to the benefits and costs of providing coverage for home infusion therapy under the Medicare program, including an assessment of the possibility of**

achieving savings through avoided or shortened hospital or nursing home stays as a result of Medicare coverage of home infusion therapy

Though there is some literature on the costs of home infusion, most studies are dated and do not estimate the costs of a home infusion program under Medicare's FFS payment systems. According to our analysis, whether home infusion yields Medicare savings or costs for an individual beneficiary depends on the setting where the beneficiary otherwise would have received infusions, the payment rates established for home infusion and how they compare with the payment rates in that alternative setting, how frequently the drug is infused, and how often home nurse visits are needed. To the extent that some beneficiaries are admitted to SNFs because of the out-of-pocket costs associated with home infusion, opportunities likely exist to achieve savings by providing care for these beneficiaries at home. Shifting infusions from HOPDs or physician offices to the home could yield net savings or costs depending on how frequently nurse visits are needed, how drug payment rates compare under Medicare Part B and Part D, and the payment rates established for home infusion. Savings from substituting home infusion for home health episodes may be possible in some circumstances. Inpatient hospital expenditures are not likely to be a significant source of savings because we do not anticipate substantial substitution of home infusion for hospital admissions. Some patients might be discharged earlier from the hospital as a result of broader home infusion coverage, but the impact on Medicare expenditures for such patients would vary, with savings expected for a small subset and little change or increased expenditures expected for most.

For expanded home infusion coverage to realize overall savings for Medicare, shifts in site of service would need to result in savings that exceed the additional costs associated with the crowd-out effect (i.e., Medicare assuming responsibility for home infusion services that otherwise would have been paid by other insurers or beneficiaries) and the woodwork effect (i.e., coverage of home infusion leading to more beneficiaries using IV drugs when they otherwise would have been treated with other therapies). The cost implications of broader home infusion coverage vary by drug. As a result, a targeted expansion of home infusion coverage focusing on a subset of drugs

would have more likelihood of savings than a broad expansion. However, a lack of data impairs our ability to determine whether net savings would result, even in the case of a targeted expansion (e.g., antibiotics, or IVIG for PID). Although it is unsatisfactory to be unable to draw a conclusion about net savings or costs, it might be possible to collect additional information to fill in some of the data gaps, but it would be difficult to collect all the data needed.

2. An assessment of sources of data on the costs of home infusion therapy that might be used to construct payment mechanisms in the Medicare program

Data on the costs associated with providing home infusion services are limited. An industry-sponsored study that estimated the per diem costs of home infusion has methodologic limitations that reduce its utility for rate setting. Data on Medicare payment rates for similar services such as home health care and DME might be a source of some benchmarks. Another avenue for obtaining cost information might be competitive bidding. Also, the feasibility of obtaining data on providers' acquisition costs or manufacturers' sales prices for equipment and supplies could be explored.

3. An assessment of private payment methodologies used by Medicare Advantage plans and private health plans for the provision of home infusion therapy and their applicability to the Medicare program, with reference to recent work by the Government Accountability Office

We found that the most common payment method used by private health plans and MA plans included a payment for drugs, a separate payment for nursing as needed, and a per diem payment covering supplies, equipment, pharmacy services, and additional services. GAO did not discuss the applicability of this payment method to Medicare. This payment method could be applicable to Medicare depending on the payment rate chosen. Providers we interviewed described a wide range of payment levels for per diem services. Other payment methods may also be possible, including bundling (as part of an episode of care or bundling nursing along with supplies and equipment as part of a per diem rate) and competitive bidding.

Some technical issues would have to be resolved with any methodology selected. For example, some drugs are currently covered under Part B or Part D, using different payment methods. Services covered under the Part D dispensing fee overlap with some of the services provided under the per diem paid by private plans. In designing a payment method, policymakers would also need to be cognizant of the potential for increased expenditures because of the crowd-out effect and the woodwork effect.

4. A discussion of any issues surrounding the potential abuse of a home infusion therapy benefit in Medicare

Private plan representatives did not report any evidence that fraud and abuse are more prevalent in the area of home infusion than in any other type of service. All plans use utilization management techniques, particularly prior authorization, to ensure that home infusion is provided appropriately. Plans generally ask physicians to report the diagnosis, prescribed drug, dosage, and expected duration of therapy. They may also request information about the patient's age, sex, and weight. Some plans require separate approval for a schedule of nursing visits. One health plan described the need to look closely at utilization of home infusion to ensure it is appropriate and noted this kind of oversight would present a challenge for FFS Medicare. In general, Medicare has had less ability to monitor care provided in the home than in facility settings and it has been more difficult to create payment systems with incentives

for appropriate utilization. While private payers have not found fraud to be a problem in the home infusion industry, a broad, unmanaged expansion of Medicare FFS coverage could lead to fraudulent actors entering the field.

Although we did not make any recommendations, we discussed two approaches for increasing access to home infusion: filling in the gaps in current coverage and setting up a demonstration project to test the effects of providing an integrated home infusion benefit for beneficiaries needing infused antibiotics. Each approach has advantages and drawbacks. We examined the gap-filling approach by considering policies for IVIG under Part B and antibiotics under Part D. We examined the integrated benefit approach through a demonstration project that would test quality and efficiency under an integrated home infusion benefit for antibiotics.

To ensure appropriate utilization, a project testing provision of a home infusion therapy benefit would require management controls such as prior authorization. This project could test the ability of CMS to administer a targeted prior authorization policy designed to improve quality of care and reduce costs. Since prior authorization can be labor intensive and require considerable resources, it would be a challenge for CMS. However, targeted prior authorization could be a useful tool to improve quality and control inappropriate utilization not just in home infusion but in other areas as well. If CMS is able to administer a targeted prior authorization program, benefits would accrue to beneficiaries and the program as a whole. ■

Endnotes

- 1 While home infusion typically involves IV infusions, some home infusion drugs are infused in other ways (e.g., subcutaneous infusion of insulin or immune globulin via a pump).
- 2 Drug administration services and drugs are generally bundled into the SNF prospective payment system payment, with the exception of some drugs (primarily chemotherapy) that are separately billable under Part B.
- 3 Whether a drug is covered by Medicare Part B or Part D depends on several factors, such as how the drug is administered, the location where it is administered, who procures the drug, and in some cases the patient diagnosis. Infusion drugs that are considered not usually self-administered are covered by Part B when procured by a physician or HOPD and furnished in an office or facility. Part B also covers certain drugs infused in the home, including drugs that require a DME pump and for which home infusion has been determined reasonable and necessary; IV immune globulin for primary immune deficiency; and total parenteral nutrition for a permanently nonfunctioning gastrointestinal tract. Drugs not covered by Part B in a particular circumstance are potentially covered by Part D subject to the Part D plan's formulary and any prior authorization criteria.
- 4 Coverage of IVIG for home infusion under Part B works differently than other home infusion drugs covered under Part B. Part B covers only the IVIG, not the supplies or equipment. For beneficiaries who are homebound, the home health benefit covers nursing and, in some circumstances, limited supplies.
- 5 For DME drugs that did not exist as of October 1, 2003, Medicare pays 95 percent of the AWP at the product's launch. Since AWP is not a market-based price, this approach has the potential to lead to high payment rates for new products to the extent that they are developed and meet DME coverage criteria.
- 6 The net cost to Part D for these drugs would be lower than our \$422 million estimate because it is not reduced to reflect any rebates Part D plans may receive from drug manufacturers. This estimate reflects IV drugs paid by Part D for beneficiaries who did not reside in a long-term care facility when the prescription was filled. We assume these IV drugs were administered in the home, although we cannot rule out the possibility that some drugs may have been transported ("brown bagged") by beneficiaries to physician offices or HOPDs for administration.
- 7 It is uncertain whether lower Part D cost sharing for low-income subsidy enrollees, Medicaid coverage for home infusion supplies and other services, differences in patient characteristics, or other factors contribute to the higher use of Part D infusion drugs among low-income subsidy enrollees overall and within prescription drug plans.
- 8 Sometimes the referral goes to a home health agency, which coordinates with a home infusion provider.
- 9 Some Part D plans require physicians to submit a Part B claim and have it denied before they will cover the drug under Part D.
- 10 According to the National Home Infusion Association the per diem payment is intended to cover a broad range of services and costs such as dispensing (e.g., checking drug interactions, compounding, maintaining a "clean room"); clinical monitoring (e.g., reviewing test results and recommending medication changes); care coordination (e.g., coordinating with physician, home health agency, other providers; 24-hour/7-day phone availability of nurse and pharmacist for questions and issues); supplies and equipment; and administrative costs (e.g., verifying insurance, obtaining prior authorization, coordinating benefits, training staff, quality assessment, accreditation). Some of the services included in this definition of the per diem are services Medicare would consider covered under the Part D drug benefit (e.g., operational and administrative costs associated with dispensing a drug).
- 11 Both plans had a reconciliation process that took place periodically if actual costs were far off the expected amount. The plan that provided the capitation to a home infusion provider carved out certain low-frequency and high-cost drugs from the capitation.
- 12 Under the hospital outpatient prospective payment system, most drugs with a cost per day greater than \$75 are paid the ASP plus 4 percent in 2012. An exception is new drugs and biologicals that receive pass-through status and are paid the ASP plus 6 percent during the first two to three years after their launch.
- 13 The four resource utilization groups that seem to be most relevant to patients admitted to a SNF solely for home infusion have payment rates in 2012 of approximately \$223, \$262, \$281, and \$471. Data specific to patients receiving infusions are not available, but overall the percentage of SNF patients is highest in the lower paying case-mix groups.
- 14 One way Medicare inpatient hospital payments can be affected by length of stay is if the cost of a case becomes so high it reaches high-cost outlier status and Medicare provides outlier payments. In such a case, if length of stay

- were reduced because of broader home infusion coverage, Medicare outlier payments to the hospital might be reduced. However, savings from a reduction in outlier payments have only a short-term effect (two years) because once Medicare has data showing the unexpectedly lower outlier payments, Medicare recalibrates the outlier threshold for future years to result in outlier payments being a projected 5.1 percent of total DRG payments. Our interviews suggest that it is rare for a Medicare patient to receive multiweek infusions in the hospital when home care would be appropriate, so reductions in outlier payments are not likely to generate significant short-term savings.
- 15 When payments are prorated, hospitals are generally paid two times the per diem for the first day and the per diem for each subsequent day, with payment capped by the full DRG payment. Because of the higher payment on the first day, the average amount saved each day below the geometric mean length of stay is less than the per diem.
 - 16 It is unclear if under existing regulations the post-acute transfer policy applies to a patient discharged home to receive infusions but not provided through the Medicare home health benefit. If home infusion coverage were expanded, steps could be taken to ensure that the post-acute care transfer policy applies to patients discharged home for infusion therapy.
 - 17 For most IV drugs, we would not expect patient-driven demand to increase use, but for some drugs that may not be the case (e.g., pain medications and IVIG for off-label uses).
 - 18 The home health 60-day episode payment amount cited reflects the average home health payment based on claims analysis. The 60-day episode payment rate under the home health PPS is not reduced for episodes less than 60 days. As long as more than four visits are provided, the entire episode payment is made.
 - 19 Our hypothetical example focuses on vancomycin, the most common IV antibiotic covered by Part D and a very low-cost product. Cost difference across settings would likely differ for a drug with a higher cost. For example, daptomycin typically costs more than \$200 per day. In SNFs, nonchemotherapy drugs like daptomycin are not paid separately. Thus, depending on the beneficiary's case-mix group (the most relevant for these patients have 2012 payment rates of about \$223, \$262, \$281, and \$471), the Medicare payment to a SNF could be less than payments for home infusion, particularly if the beneficiary received assistance with infusion services through the Medicare home health benefit. Whether Medicare beneficiaries are receiving daptomycin in SNFs is unknown. We heard anecdotally in a few interviews about SNFs' reluctance to accept patients who need high-cost drugs.
 - 20 In our hypothetical example, if we had assumed five nurse visits per week instead of two nurse visits per week, home infusion would have been more expensive than the HOPD under the scenario with a \$75 per diem amount.
 - 21 From interviews, we heard that it was not typical to have daily nurse visits for antibiotics, but some plans indicated they would authorize daily visits if a patient needed them while others indicated they might consider such a patient better suited for receiving infusions in an alternative setting. It is unknown how much nursing would typically be needed among Medicare beneficiaries, who are older and may have more functional limitations than the working age population.
 - 22 When comparing costs in an HOPD with home infusion with nursing provided through the Medicare home health benefit, it is important to note that our estimate of costs associated with care in an HOPD includes only the costs related to infusions. If a patient was getting assistance with infusions and wound care through home health care, the relevant comparison point for the HOPD would be our estimate of infusion costs plus an estimate of the costs of wound care provided by an HOPD.
 - 23 Changing other aspects of our hypothetical scenario would also change the savings estimates. A shorter course of treatment would increase the payment differential between SNFs and home infusion because there would be fewer days with beneficiary cost sharing of \$144.50 per day (days 21 and onward in SNFs). Similarly, a longer course of treatment would decrease the differential between SNFs and home infusion. If we assume more nurse visits per week or a higher payment rate for nurse visits or home infusion supplies and equipment, the cost of home infusion increases.
 - 24 Our assumption of a minimal woodwork effect for IVIG is due to the focus on a specific diagnosis: PID covered by Part B. Part D covers IVIG used for other purposes, including a number of off-label uses with varied levels of evidence supporting its use. If we were analyzing the cost implications of expanded home infusion coverage for Part D–covered IVIG, we would expect a substantial woodwork effect.
 - 25 In April 2012, CMS announced that it planned to include infusion pumps and supplies in an upcoming round of the competitive bidding program.
 - 26 If beneficiaries who have existing coverage choose to opt out, the demonstration would understate the extent of the crowd-out effect that would occur if these services were permanently added to the Medicare benefits package and an evaluation of a demonstration would likely need to make an adjustment to take this factor into account.

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