CHAPTER 9

Medicare payments for outpatient drugs under Part B

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In this chapter

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- Issues raised by the current payment system
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This chapter looks in depth at one service—Medicare-covered outpatient drugs—for which the Medicare payment method is flawed. Three major problems are that Medicare payments far exceed provider acquisition costs; the system creates incentives for manufacturers to raise their list prices, resulting in increased Medicare payments; and drug administration fees do not reflect the true costs of providing drugs to beneficiaries.

Policymakers are considering how to change the current system. We examined payment methods that other public and private purchasers have developed for physician-administered drugs. We also analyzed the alternatives suggested by the policy community, which include benchmarking methods, payment based on invoice prices, and competitive bidding. Several variants of benchmarking methods are possible, including benchmarking payment amounts to transaction prices that could be audited. Combination approaches based on the competitiveness of the therapeutic drug class are also possible. While each method has advantages and disadvantages, any one of these alternatives would be a significant improvement over the current payment system.

Spending for outpatient drugs covered under Medicare Part B has grown rapidly. Preliminary estimates suggest that expenditures reached $8.5 billion in 2002, an increase of nearly 35 percent over 2001 totals. For the past four years, expenditures have increased annually by more than 20 percent. This growth reflects increased use of the drugs, rising prices, and incremental coverage expansions. Medicare-covered outpatient drugs are mainly used in cancer treatment, dialysis, organ transplantation, and hemophilia. Medicare also covers some outpatient drugs used with durable medical equipment such as infusion pumps and nebulizers.

Medicare pays providers 95 percent of the average wholesale price (AWP) for each covered drug. Despite its name, AWP does not represent the average wholesale price but rather can be thought of as a manufacturer's suggested list price. AWP is not defined in law or regulation and does not have to correspond to any transaction price or average transaction price. A series of studies by the General Accounting Office (GAO) and the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) showed that the current Medicare payment method leads to payments that far exceed providers' costs (GAO 2001b; OIG 2001, 1997, 1996). In some cases, beneficiaries' coinsurance payments alone exceed the price physicians and other providers paid for the drugs.

This chapter describes the current payment method and looks at the potential alternatives being considered by the policy community. We examine the mix of drugs covered by Medicare and analyze trends in spending and provide an overview of the legislative and regulatory history of the payment system, including recent administrative steps taken by CMS. We focus on three problems with the payment system: Medicare payments far exceed provider acquisition costs; the system creates incentives for manufacturers to raise list prices; and high drug prices may, in part, subsidize drug administration fees, which may not reflect the true cost of providing drugs to beneficiaries.

We present some alternatives to reform the Medicare payment system, and analyze how they would affect Medicare payments for covered drugs, how likely they are to affect beneficiary access to needed therapies, what administrative costs they would entail, and how they might affect the operation of the wider pharmaceutical market. While all payment methods have advantages and disadvantages, each option analyzed would be a significant improvement over the current payment system. Most would eliminate manufacturer incentives to raise list prices. Finally, we examine payment methods developed by other public and private payers for physician-administered drugs. These methods provide additional insight into alternatives to the Medicare payment system.

Coverage and spending

Medicare spending for Part B drugs has increased rapidly in recent years, growing by 26 percent in 2001 with corresponding increases in beneficiary obligations for copayments. Beneficiaries who receive these drugs are responsible for paying 20 percent coinsurance after they meet the annual Part B $100 deductible. CMS projects that expenditures totaled $8.5 billion in 2002, an increase of nearly 35 percent.[1] Increased spending is associated with recent coverage expansions. Spending for Part B drugs is highly concentrated. The top 35 drugs accounted for almost 90 percent of drug spending and three specialties—hematology oncology, medical oncology, and urology—accounted for more than half of total billing in 2001.

Which drugs are covered?

In general, Medicare covers drugs administered in physician offices, used as part of durable medical equipment or infusion devices, as well as some oral drugs used following organ transplants. Of the top 20 drugs covered by Medicare in 2001, 7 received Food and Drug Administraton (FDA) approval in 1996 or later.

Drugs currently covered

Under Part B, Medicare covers about 450 outpatient pharmaceutical products and biologics. Spending is highly concentrated among these products. Thirty-five of the covered drugs account for 88 and 95 percent of Medicare drug spending and drug claims volume, respectively. The top 20 drugs covered under Part B are shown in Table 9-1. They accounted for about 77 percent of Part B drug expenditures; nonend-stage renal disease erythropoietin[2] alone accounted for more than 12 percent.

Not generally available through retail pharmacies, these drugs are provided by physicians in their offices or through pharmacy suppliers that provide drugs used with durable medical equipment. They include:

- drugs not self-administered and furnished incidental to a physician's service, such as prostate cancer drugs;
- certain cancer and antinausea drugs available in pill form;
- blood clotting factor;
- immunosuppressive drugs used following organ transplants;
- erythropoietin used to treat anemia in end-stage renal disease patients and cancer patients;
- drugs used as part of durable medical equipment or infusion devices like the albuterol used in nebulizers for asthma and other pulmonary diseases; and

1 Expenditure totals for 2002 are still preliminary. These totals represent carrier paid drugs and do not include intermediary paid drugs including drugs dispensed in outpatient departments of hospitals and freestanding dialysis facilities (see text box, p. 155).

2 The Congress established a separate payment rate for erythropoietin supplied to end-stage renal disease patients in dialysis facilities (see text box, p. 155).

TABLE 9-1

Top 20 drugs covered by Medicare Part B, by share of expenditures, 2001

Drug name	Clinical indications	Type of competition	Date of FDA approval	Percent of Part B drug spending
Non-ESRD erythropoietin	Anemia	Multisource; biological	1989	12.1%
Leuprolide acetate suspension (Lupron)	Prostate cancer	Multisource	1985	10.4
Ipratropium bromide	Asthma and other lung conditions	Generic	1993	7.3
Goserelin acetate implant (Zolodex)	Prostate cancer	Sole source	1989	6.8
Albuterol	Asthma and other lung conditions	Generic	1982	5.5
Paclitaxel injection*	Cancer	Multisource	1992	4.2
Rituximab	Non-Hodgkins lymphoma	Sole source biological	1997	4.2
Pamidronate disodium*	Cancer related	Sole source	1991	3.0
Infliximab	Rheumatoid arthritis, Crohn's disease	Sole source biological	1999	3.1
Docotaxel	Cancer	Sole source	1996	2.6
Carboplatin injection	Ovarian carcinoma	Sole source	1989	2.6
Filgrastin injection	Cancer	Multisource biological	1991	2.5
Irinotecan injection	Cancer	Sole source	1996	2.5
Gemcitabine Hcl	Cancer	Sole source	1996	2.1
IV immune globulin	Immunodeficiency for transplants; HIV	Multisource biological	early 1980s	1.8
Dolasetron mesylate	Cancer related	Sole source	1997	1.8
Hylan G–F 2 injection	Pain from osteoarthritis	Multisource	1997	1.3
Unclassified drugs	N/A	N/A	N/A	1.0
Leucovorin calcium injection	Cancer	Generic	before 1982	1.0
Influenza vaccine	Influenza prevention	Multisource biological	N/A	1.2

Note: ESRD (end-stage renal disease), FDA (Food and Drug Administration), HIV (human immunodeficiency virus), IV (intravenous), N/A (not applicable).
*Now have generic equivalents available.

Source: MedPAC analysis of 2001 Medicare claims data from CMS and unpublished FDA data.

- osteoporosis drugs provided to certain beneficiaries by home health agencies.

Physician-billed drugs account for the largest share of program spending. In 2001, physician claims accounted for more than 80 percent of total Medicare expenditures for outpatient drugs. This category includes many brand name drugs and biologicals for which no competition exists, and that tend to be more expensive than generic drugs (see text box, p. 153).

Billing is concentrated in certain specialties (Figure 9-1, p. 152). Most claims are submitted by oncologists. Three specialties—hematology oncology, medical oncology, and urology—submitted claims for 58 percent of total billing for Part B-covered drugs. Primary care physicians submitted claims for an additional 6.4 percent of covered drugs. For some specialties, payments for Part B drugs represent a large portion of total Medicare payments. In 2001, 72 percent of all Medicare payments to hematology oncologists and medical oncologists were for Part B drugs. Similarly, 64, 43, and 31 percent of Medicare payments to hematologists, urologists, and rheumatologists, respectively, were for covered drugs.[3]

Pharmacy-supplier billed drugs account for the largest volume of drug claims: Two inhalation therapy drugs, albuterol and ipratropium bromide, accounted for 88 percent of prescriptions filled by pharmacy suppliers for home administration in 1999. This category tends to contain more lower cost drugs with generic equivalents.

Medicare also pays for some outpatient drugs and biologicals provided in immunization centers and independent laboratories.

How coverage has expanded

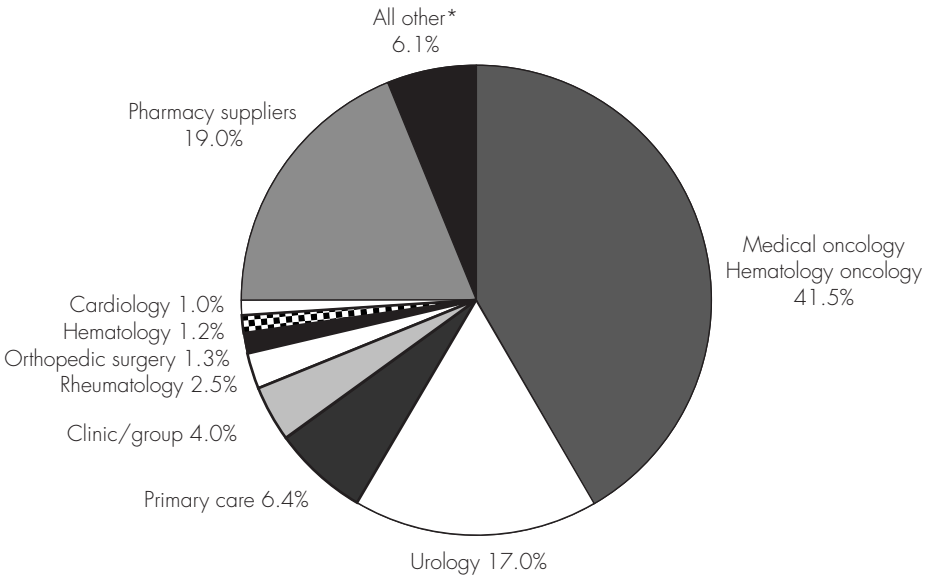
Coverage policies for Part B-covered drugs have been a continuing subject of Congressional interest and controversy. The Congress has gradually increased the quantity, type, and duration of drugs covered to address additional beneficiary needs. Although the Congress mandates the categories of drugs that Medicare covers, decisions by CMS and local carriers determine the specific drug products eligible for reimbursement. There can be significant differences in coverage for specific drugs by regional carriers.

Legislation expanded drug coverage under Part B three times in the past decade. Each legislative change has led to calls for further expansions:

3 MedPAC analysis of 2001 Medicare claims data from CMS.

FIGURE 9-1

Medicare drug spending, by physician specialties and other providers, 2001



* No other provider had expenditures equal to at least 1 percent of total Medicare drug spending.

Source: MedPAC analysis of Medicare claims data, 2001.

- Since 1993, Medicare has covered cancer drugs administered through oral dosages if injectable forms were already available, but not otherwise. This policy left gaps that led advocates to call for the coverage of all cancer drugs. For example, a new class of cancer drugs that disrupt the growth of cancer cells without damaging surrounding tissues is being developed. The first such drug, Gleevec, approved for treatment of chronic myelogenous leukemia, came on the market last year. Because this breakthrough drug has never had an injectable form, it is not covered by Medicare.

- A provision in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) expanded the class of drugs eligible for coverage from those that are not self-administered to those not *usually* self-administered. This policy has led to calls for broader coverage of self-injectable drugs. In May 2002, a CMS program memorandum clarified the coverage rules: Drugs delivered by intramuscular injection are covered, but drugs delivered through subcutaneous injections are not. Thus, Medicare will cover Avonex, one drug that treats multiple sclerosis, because it is delivered through intramuscular injection, but does not cover any other drugs for this condition. Carriers can make exceptions based upon a number of factors including frequency of administration, but not based on the capabilities of the individual patient. Legislation in both Houses of Congress would increase Medicare coverage for self-injectables.

- A previous expansion mandated coverage of immunosuppressives for beneficiaries receiving organ transplants. Coverage was limited to three years even though patients must continue taking these medications for the rest of their lives. A provision in BIPA removed the three year time limit for coverage. In the 107th Congress, legislation was introduced to require continuing coverage of immunosuppressives for Medicare beneficiaries, regardless of whether they received transplants while enrolled in Medicare.

Several other bills requiring incremental expansions in Part B drug coverage are before the Congress.

What is Medicare's payment policy?

Medicare has used different methods to reimburse providers and suppliers for outpatient drugs over time. Before 1992, Medicare carriers generally paid for drugs based on physicians' estimated costs as measured by the AWP. In 1992, Medicare formalized this policy and it fixed payments for covered outpatient drugs at 100 percent of AWP.

AWP and Medicare payments

Despite its name, AWP does not represent the average wholesale price. AWP can be thought of as the published suggested wholesale price of a drug or a manufacturer's suggested list price. It does not have to correspond to any transaction price or average transaction price. Actual transaction prices often reflect substantial discounts. Every drug has its own AWP. Because information about the actual prices manufacturers charge their customers is proprietary, AWPs are one of the few publicly available sources of drug prices.

AWP has never been defined in statute or regulation. Individual AWPs are compiled and reported in compendia like the Red Book and First Databank, largely on the basis of information supplied by manufacturers. Because there is no official calculation method, CMS potentially can use alternate sources of information like market surveys to establish new AWPs for setting Medicare payment rates. These rates could be tied to actual transaction prices.

Glossary of terms

Biologic: a product derived from living material—human, plant, animal, or microorganism—applicable to the prevention, treatment, or cure of diseases or injuries of humans. A company patents the *production process* for manufacturing a biologic rather than the product itself.

Biotechnology: a set of tools that employ living organisms (or parts of organisms) to make or modify products, improve plants or animals, or develop microorganisms for specific uses. Modern biotechnology includes the use of recombinant DNA and monoclonal antibodies.

- **Recombinant DNA** (rDNA or *in vitro recombination*): molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.
- **Monoclonal antibody:** laboratory-produced substances that can locate and bind to cancer cells wherever they are in the body. Many monoclonal antibodies are used in cancer detection or therapy. Monoclonal antibodies can be used alone or to deliver drugs, toxins, or radioactive material directly to a tumor.

Drug: any chemical compound used in the prevention, diagnosis, treatment, or cure of disease, for the relief of pain, or to control or improve any physiological or pathological disorder in humans or animals. Drugs produced by more than one manufacturer are called generic or multiple source. Drugs produced by one manufacturer are called single source drugs.

- **Generic drug:** identical, or bioequivalent, to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.
- **Multiple source (multisource) drug:** marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different brand names. This category includes both generic and brand name drugs.
- **Single source drug:** marketed or sold by only one manufacturer or labeler under one brand name.

Inhalation therapies: a group of respiratory treatments designed to help restore or improve breathing function in patients with a variety of diseases, conditions, or injuries.

Infusion therapies: treatments involving the administration of medications, nutrients, or other solutions into the bloodstream, under the skin, into the digestive system, or into the membranes surrounding the spinal cord.

Injection methods: Three injection methods are intramuscular, intravenous, and subcutaneous.

- **Intramuscular injection:** an injection given into a muscle of the body. CMS defines drugs delivered by this method as not usually self-administered by the patient.
- **Intravenous injection:** a process of slowly injecting fluids and drugs into a blood vessel.
- **Subcutaneous injection:** an injection beneath the skin.

Radiopharmaceutical: a pharmaceutical, biologic, or drug that contains a radioactive entity.

Therapeutic class: a group of drugs similar in chemical structure, pharmaceutical effect, and/or clinical use. There are many different ways of classifying therapeutic classes. ■

From 1992 until 1997, Medicare calculated reimbursement for covered outpatient drugs on the basis of 100 percent of the published AWPs. A continuing series of investigations by the OIG (OIG 1997, 1996) demonstrated that this method resulted in Medicare paying far more than other public purchasers for these drugs. The OIG compared the rates Medicare paid with the prices advertised in catalogues published by drug wholesalers and group purchasing organizations, the sources most physicians and pharmacy suppliers use to purchase their stock. The drugs were widely available to purchasers at prices well below AWP. After considerable debate, the Balanced Budget Act of 1997 (BBA) set payment rates for Medicare covered single source drugs and biologics at 95 percent of AWP.[4]

Current Medicare payment rates are:

- for brand name drugs produced by a single manufacturer (referred to as single-source drugs), 95 percent of AWP.

4 The President's fiscal year 1998 budget contained an alternate proposal for AWP reform.

- for drugs for which there are two or more competing brand name products (referred to as multisource drugs) or generic equivalents available, 95 percent of the lower of (a) the median AWP of all generic forms of the drug or (b) the lowest brand-name product AWP.

Coding issues

The AWP payment method has resulted in reimbursement inconsistencies among carriers.[5] The OIG found wide variation in prices paid by local carriers for covered drugs even though all payments were based on the same formula. Much of the difficulty stems from differences in how physician-administered drugs are coded by Medicare as well as many private payers. Medicare relies on Healthcare Common Procedure Coding System (HCPCS) codes to identify drugs for payment. Under this classification scheme, most covered drugs are assigned J-codes. For drugs administered outside of physician offices, other public and private payers use a coding system based on national drug codes (NDCs) maintained by the FDA. Every drug sold in the United States has a unique NDC that provides information on the chemical molecule, the drug manufacturer, dosage, dosage form, and package size. AWPs are attached to each NDC. To determine drug AWPs for purposes of Medicare payment, carriers must convert HCPCS codes into corresponding NDC codes.

While some HCPCS codes correspond to only one NDC, others can represent as many as ten. Even when a HCPCS code identifies a single drug, NDC codes might differ depending upon the size of the package from which the drug was dispensed. Carriers had to choose the AWP from a single NDC code or compute an AWP from several corresponding NDC codes. Each carrier could make a different decision. Carriers also differed in frequency of updating AWPs. In a recent study, the OIG found that carriers' payment amounts for a single HCPCS code differed by more than 10 percent. CMS recently addressed this problem by the establishment of a single drug pricer (SDP) for drugs and biologicals covered under Medicare Part B. The section on CMS efforts to reform the payment system discusses inherent reasonableness and the SDP policy.

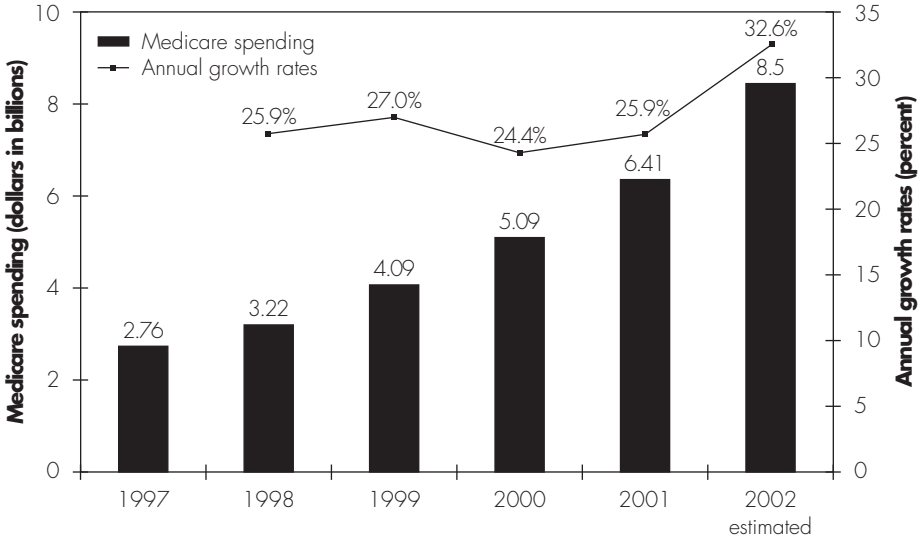
Why has spending increased?

Total spending for Medicare Part B-covered drugs (that is, program spending and beneficiary cost sharing) rose from about $700 million to $4 billion from 1992 to 1999. Between 1999 and 2000 alone, spending increased an additional $1 billion. Total spending increased by 26 percent, or nearly $1.5 billion, in 2001 to reach $6.4 billion (Figure 9-2). Expenditures for Part B drugs now equal about 3 percent of total Medicare spending (see text box at right). Preliminary estimates suggest that expenditures rose to $8.5 billion in 2002, an increase of nearly 35 percent.

The primary reason for growth in this sector is the increased volume of drugs used and the substitution of newer and more expensive medications for older therapies. More people are living with serious chronic diseases and new treatments for managing these diseases are being developed. Of the top 20 drugs covered by Medicare in 2001, 7 received FDA approval in 1996 or later (Table 9-1, p. 151). In addition, the types of new drugs under development are driving up costs. Manufacturers of breakthrough technologies for these diseases have some incentive to produce injectables rather than oral solids because they have lower drug development costs, greater potency per dose, and higher efficacy rates (Ransom 2002). Also, Medicare coverage for outpatient drugs, other than those supplied in conjunction with certain items of durable medical equipment (DME), is generally limited to those requiring physician administration.

The most significant factor driving spending growth is the emergence of an increasing number of drugs produced through the use of biotechnology. More than 80 such products have received FDA approval and over 350 additional products targeting more than 200 diseases are

FIGURE 9-2 **Medicare spending and annual growth rates for Part B drugs**



Source: Unpublished CMS data.

5 Carriers are private organizations, usually insurance companies, that serve as the government's fiscal intermediary for items and services provided under Medicare Part B.

currently in human clinical trials (AIS/PharMedQuest 2001). Not only are these products expensive when initially marketed, they face only limited competition over time because the FDA has no approval process for generic versions of biologicals.

MedPAC sponsored a study conducted by a team of researchers at NORC at the University of Chicago and Georgetown University (NORC/Georgetown 2003a) on drugs in the final stages of clinical trials. The goal was to determine if these drugs are likely to be covered under Part B under current Medicare coverage rules. Researchers identified more than 650 drugs in development by over 100 pharmaceutical and biotechnology companies, with nearly one-fourth in the late stages of development. A large number of these products are biological agents.

Researchers interviewed experts on the pharmaceutical industry to help identify important trends. They found that about 70 percent of the identified drugs are being tested for treatment of various cancers. However, they noted a trend toward the development of physician-administered drugs for other conditions. Many of these products could be eligible for Medicare coverage if they reach the market. Some are important for future Part B spending because they treat conditions with high prevalence in the elderly, such as heart disease, rheumatoid arthritis, and diabetes.

On the other hand, researchers found that the incentives created by Medicare coverage rules to develop physician-administered forms of drugs are countered by other market incentives. Patients prefer the convenience of self-administered drugs, and physicians believe that this convenience is likely to lead to better patient compliance with therapy. For many conditions, the majority of patients are covered by private insurance, not Medicare. Experts believe that on balance the trend towards self-administration more strongly influences research and development decisions than does the potential for Medicare coverage.

Drug spending in outpatient departments of hospitals and freestanding dialysis facilities

While this chapter focuses on drugs administered in physician offices or provided by pharmacy suppliers, Medicare Part B also pays separately for some drugs provided through outpatient departments of hospials and in freestanding dialysis facilities. The expenditure totals for Part B drugs examined in this chapter do not include payments for these drugs.

In 2001, freestanding dialysis facilities billed Medicare for more than $2 billion for drugs. This total includes $1.4 billion for erythropoietin, an anemia drug paid at a Congressionally mandated rate for end-stage renal disease (ESRD) patients.[1] In addition, CMS estimates that Medicare expenditures for drugs and radiopharmaceuticals eligible for pass-through payments under the outpatient department prospective payment system totaled $370 million in 2002.

Previous MedPAC reports analyzed some of the reimbursement issues associated with drugs dispensed in outpatient departments and freestanding dialysis facilities.[2] Any change in payment methods for Part B drugs should take into account ongoing efforts to modify the payment systems for outpatient drugs in these settings. ■

1 By statute, Medicare pays $10 per 1,000 units for erythropoietin administered to ESRD patients. The average wholesale price –5 percent formula is applied for purchase of erythropoietin provided other than through a dialysis facility and for all other conditions including cancer.

2 These issues are analyzed in detail in previous MedPAC reports to the Congress (MedPAC 2002, 2001).

Issues raised by the current payment system

Three issues raised by the current payment system have received particular public attention:

- Payments far exceed provider acquisition costs.
- Manufacturers have an incentive to raise list prices.
- Payments for drug administration may be too low.

AWP and provider acquisition costs

After implementation of the 1997 BBA reform, continued investigations by the OIG (2001), the Department of Justice, and the GAO (2001b) concluded that Medicare still paid for drugs at rates well above providers' acquisition costs. In a report issued September 21, 2001, the GAO examined prices available to physicians through wholesaler and group purchasing organization catalogues. The GAO (2001b) concluded that widely available prices at which both physicians and pharmacy-suppliers could purchase drugs were substantially below AWP—catalogue prices ranged from 13 to 86 percent below AWP. Even physicians who billed Medicare for only a few covered drugs reported receiving discounts equal to or greater than the

widely available discounts advertised in these catalogues. Using catalogue prices for 31 high volume drugs for which data was available, the GAO (2001b) concluded that in 2000 Medicare paid at least $532 million more than physicians' acquisition costs for these drugs and $483 million more than pharmacy suppliers' costs. These figures do not include rebates and other discounts that would have lowered still further the final sales price paid by physicians and suppliers. In the course of our research, MedPAC learned that these discounts are of increasing value.

- In 2000, average catalogue prices for albuterol and ipratropium bromide, drugs that accounted for 88 percent of pharmacy-supplier drug claims, were 85 and 78 percent less than AWP, respectively. Although the cost of an individual dose of either of these drugs was not high, Medicare expenditures for them totaled more than $500 million.

- The OIG's recent study (2001) of the 24 drugs most commonly paid for by Medicare in 2000 determined that Medicare paid $587 million more than the prices paid by physicians and suppliers for these drugs and almost $2 billion more than prices available through the federal supply schedule (FSS). Had beneficiaries realized these savings, their total copayments would have been $400 million less.

Estimates of the difference between Medicare payments and providers' actual costs are problematic. The net price providers pay for covered drugs is not clear at the time of purchase. For example, physicians and suppliers may belong to group purchasing organizations that negotiate with manufacturers or wholesalers. Negotiated agreements may include rebates and other discounts that depend on the volume of purchases made over time or changes in market share for a particular product. Payment of the rebates follows a negotiated time period.

The phenomenon of a gap between AWP and actual wholesale prices is not limited to Medicare. The market for prescription drugs is very segmented by purchaser. Manufacturers typically offer different prices for different classes of trade.[6] For example, hospitals generally pay less for drugs than retail drugstores do. Further, within each market segment, manufacturers negotiate individually with purchasers such as drug stores, health plans, and pharmacy benefit managers. Pharmacy benefit managers also negotiate with pharmacies over the amount that they will reimburse pharmacies on behalf of their clients. Thus the actual price charged to any one customer is a closely guarded trade secret. Under these circumstances, AWP is a benchmark for negotiations. For example, a typical contract between a pharmacy benefit manager and a pharmacy might call for reimbursement for drugs according to a formula based on AWP minus 13 percent plus a dispensing fee. However, the Medicare payment method has resulted in increasing gaps between AWPs and provider purchase prices.

A study conducted by Hoerger and Wittenborn (2002) for CMS found considerable differences in average discounts available for Part B drugs based upon whether the drug was generic or a brand name innovative product. Using data from IMS Health, a large pharmaceutical market research and consulting firm, researchers looked at prices different purchasers paid for 30 of the top 38 Medicare drugs for which data were available, by payment level in 2000. IMS Health collects transaction prices paid to manufacturers and wholesalers for drugs for specific classes of trade. These prices do not include rebates and discounts that took place after the purchase. Using these data, researchers calculated the difference between Medicare payment rates and average transaction prices for clinics (which include physician practices.) All but one of the reported prices were lower than the Medicare payment rates.[7] Prices varied, however, by whether the drug was a generic or brand name product. Transaction prices averaged 83.1 percent below Medicare rates for albuterol and 70.4 percent below for ipratropium bromide, the two generic drugs with the highest Medicare expenditures. For single source brand name drugs, discounts typically ranged from 13 to 20 percent below Medicare rates. However, because brand name drugs tend to be more expensive than generic drugs, the actual difference between Medicare payment and drug costs is likely to be greater for brand name drugs.

Incentives for increasing AWPs

In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers. Although the manufacturer's profit per dose will not increase with the rise in the listed price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor. At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of

6 Classes of trade included hospitals, HMOs, clinics, mail-order pharmacies, food stores, chain stores, independent pharmacies, home health agencies, long-term care facilities, and federal facilities.

7 The exception was imiglucerase. Clinic prices were, on average, 0.1 percent higher than Medicare payment rates.

$740, was sold to physicians for $7.50 per dose. The beneficiary's copayment (about $150) was about 20 times providers' acquisition cost.

Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy (see text box, p. 158). They leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share.

On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers. If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products. It is too soon to know how these guidelines will affect pharmaceutical company marketing practices.

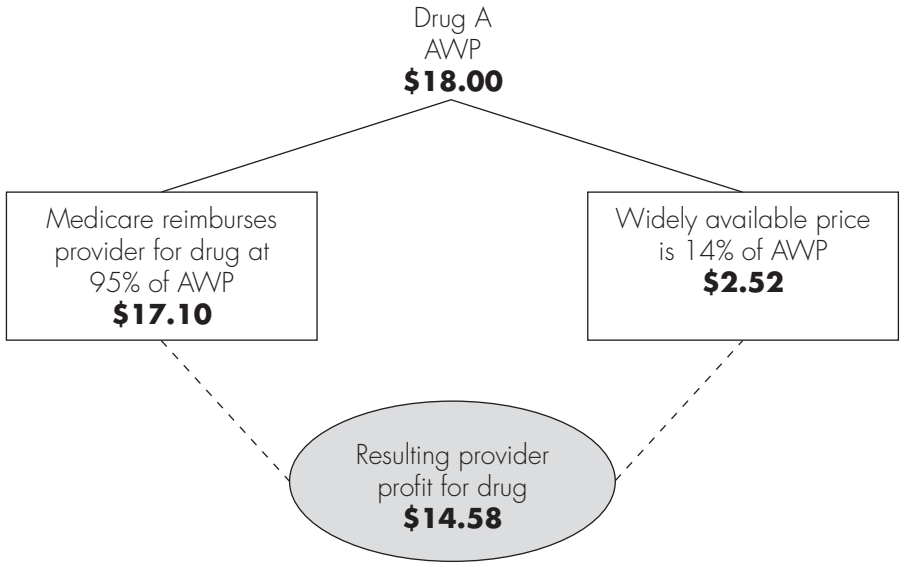
The relationship between AWP, Medicare payments, and provider profits are shown in Figures 9-3 and 9-4. These examples are for illustrative purposes only and do not represent any specific drugs.

Drug administration fees and cross subsidies

In addition to reimbursement for the cost of covered drugs, the Medicare physician fee schedule includes fees for drug administration. These payments may be too low, particularly for administration of chemotherapy. Physicians have argued that they need the high payments for drugs to offset inadequate payments for provision of these services.

The focus of controversy is the calculation of practice expenses for the administration of chemotherapy. Components of practice expenses in the physician fee schedule include compensation for nonphysician staff, rent and utilities, equipment, and supplies. To establish the practice expense component of the physician fee schedule, CMS first estimates the total allowable expenses for physician practices and then

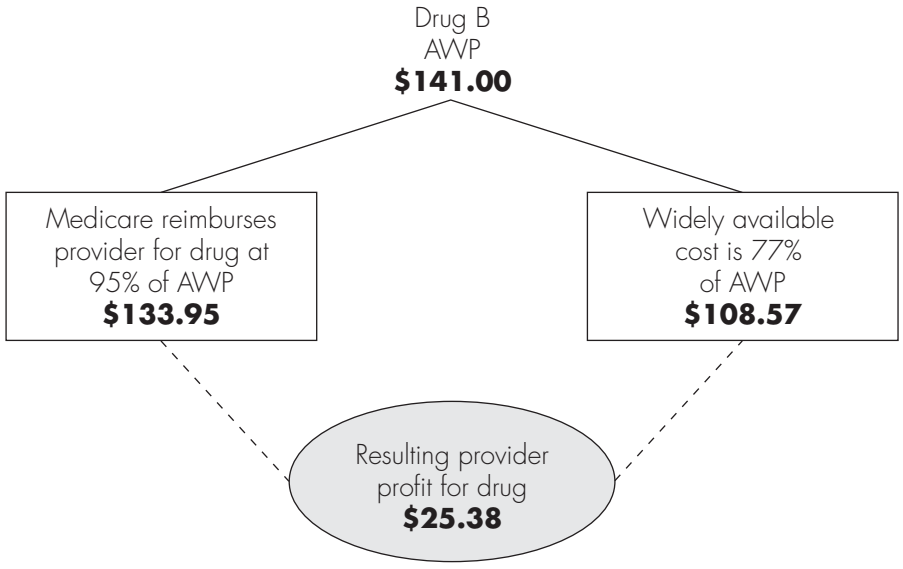
FIGURE 9-3 **Medicare payments vs. provider costs: an example for a generic drug**



Note: AWP (average wholesale price).

Source: Based on information from U.S. General Accounting Office, Medicare payments for covered outpatient drugs exceed providers' cost. September 2001.

FIGURE 9-4 **Medicare payments vs. provider costs: an example for a brand name drug**



Note: AWP (average wholesale price).

Source: Based on information from U.S. General Accounting Office, Medicare payments for covered outpatient drugs exceed providers' cost. September 2001.

allocates the estimated expenses to each service performed by physicians.

Each specialty's total practice expense pool is derived from Medicare claims data and data collected by the American Medical Association's Socioeconomic Monitoring System (SMS) survey, collected from 1995 to 1999. Using the survey, CMS calculated average expenses per physician work time for practice expenses. Hourly expenses are multiplied by the total hours spent by all physicians in each specialty treating Medicare beneficiaries to establish each specialty's practice expenses.

Once the practice expense pools are created, CMS allocates them to specific services. In doing so, CMS distinguishes between direct and indirect expenses. Direct expenses are supplies, equipment, and nonphysician clinical staff. To allocate the direct expense pools, CMS uses detailed data on the direct expenses that physicians incur in providing specific services.

Allocation of indirect expenses for administrative labor, office, and other expenses not directly attributable to specific services is more difficult. For most services, CMS allocates indirect expense pools to specific services based on their direct expenses and the fee schedule's relative weights for physician work. For other services, including chemotherapy administration, CMS developed an alternate practice expense method because they are not typically provided by physicians and, therefore, do not have relative weights for physician work.[8] The alternate method results in the creation of a separate practice expense pool for all nonphysician services. The pool is then distributed on the basis of historical charges for each service. Specialties can opt out of this method for specific services and have payments determined through the method used for other services that include physician work.

AWP and the courts

In October 2001, TAP Pharmaceutical Products, Inc. pleaded guilty to conspiring to violate the Prescription Drug Marketing Act. The central issue in the case was the allegation that TAP had encouraged urologists to bill Medicare for free samples provided by the company. TAP markets Lupron (leuprolide acetate suspension), a treatment for prostate cancer. Lupron competes with another drug called Zolodex (goserlin acetate implant). In 2001, expenditures for Lupron and Zoladex were, respectively, the second and fourth highest of all drugs covered under Part B.

Payments based on the easily manipulated average wholesale price (AWP) have allowed marketing abuses by manufacturers of these drugs. In the civil suit, the government alleged that the company had set AWPs far above the price that any of its customers paid and encouraged physicians to take advantage of the difference by billing Medicare for the AWP minus 5 percent. As part of its settlement with the federal government, TAP agreed to pay $875 million dollars to resolve criminal and civil liabilities in connection with its pricing and marketing of Lupron. More than a dozen former TAP employees are still under indictment for using kickbacks and bribes to get doctors to use Lupron rather than Zolodex. This litigation also has led to further lawsuits by the Attorneys General in many states. These as yet unresolved suits focus on the discrepancy between AWPs and the actual acquisition prices available to retailers.

Similar charges have been filed against the makers of Zolodex. One physician pleaded guilty to billing Medicare for between $30,000 and $70,000 for free samples he received from the manufacturer (Bureau of National Affairs 2002). ■

However, critics have raised issues about the method of allocating indirect expenses for chemotherapy administration. Two potential problems have been identified. First, some oncology representatives believe that practice expense data derived from the original SMS survey did not accurately reflect the mix of oncology practices, so the practice expense pool was underestimated. Specifically, they believe that oncologists who responded to the survey must have been disproportionately in practices that did not give chemotherapy in their offices, so they did not have the direct expenses of nursing, supplies, and equipment.

Second, supply expenses for chemotherapy were underestimated. The original tabulations included the cost of drugs used in chemotherapy in the total cost of supplies. Since drugs are paid for separately, they were subsequently removed. CMS then substituted the average supply expenses reported for all specialties instead of a number specific to chemotherapy supplies. GAO (Scanlon 2001) suggests that this number might be too low given the level of supplies necessary for the administration of chemotherapy.

GAO recommended that CMS use the basic method to compute practice expenses for all services and develop more accurate data to estimate supply expenses for oncologists. GAO estimated

8 The GAO (2001a) notes that overall practice expense payments for oncology are 8 percent higher than they would have been had the previous charge-based system remained in effect in 2001.

that these changes would increase payments to oncologists by about $51 million per year (Dummit 2002). However, making these changes within current statutory authority would be difficult because of budget neutrality provisions in the fee schedule. Increases in practice expenses for administration of chemotherapy would lower fees for other services, including services performed by oncologists.

Estimates of the additional budgetary impact of adjusting the practice expense component of chemotherapy are very controversial. Oncologists believe that the CMS and GAO estimates do not take into account their true costs. They emphasize the deficiencies of the SMS survey, and also suggest that these expenses would be higher than in 1998 because of changes in the way chemotherapy is delivered. In addition, they believe that they have more nonbillable activities that are not included in the pool of practice expenses, including patient monitoring.

CMS allows specialty societies to submit new practice expense surveys, and the American Society of Clinical Oncology (ASCO) submitted a new survey. A Lewin Group analysis for CMS pointed out concerns with the resulting data: The survey showed more than a 300 percent increase in "other" expenses compared with the 1998 survey. The data also reflected extraordinarily high clerical and clinical staff expenses. In December 2002, CMS announced that it was not going to accept the survey at that time (CMS 2002).

In response, ASCO questioned Lewin's methodology. For example, they argued that the survey category of clerical workers included high-salary administrators, transcribers, and other office workers. ASCO also emphasized that the survey results for "other" expenses fell within the range of estimates for this category provided by other specialties. At this time, discussions between CMS and ASCO continue.

Other providers have also argued that high payments for drugs were necessary to offset inadequate or lack of payments for services. As with physicians, pharmacy suppliers report that reimbursements received for covered drugs are necessary to offset the uncovered expenses incurred in providing services to beneficiaries. Services provided by pharmacy suppliers include compounding many of the drugs used, responding to emergencies, patient education in the use of the required equipment, and general monitoring of the patient's health status. In general, these are noncovered services and pharmacy suppliers cannot bill for them. Medicare does provide a dispensing fee for one drug type—inhalation therapy drugs—but no similar payment for other covered drugs like infusion therapy or covered oral drugs.

One area of concern is the provision of clotting factor to Medicare beneficiaries with hemophilia. Clotting factor is provided in hemophilia treatment centers or through homecare companies. Medicare may pay as much as $200,000 annually on clotting factor for a patient with severe hemophilia. For the beneficiary, this would mean coinsurance payments totaling $40,000. While Medicare payments for clotting factor exceed provider acquisition costs, Medicare makes no payment for providing clotting factor to hemophilia patients. Dispensing costs for clotting factor include inventory management, storage, and shipping. In addition, infusion of clotting factor requires needles, syringes, and tourniquets. Medicare does not pay for the cost of any of these supplies. GAO (2003) has recommended that Medicare establish a fee for these costs if payments for clotting factor are reduced to a level closer to provider acquisition costs.

Reform efforts

The Administration and the Congress have tried repeatedly to reform Medicare's payment methods for covered outpatient drugs. For example, the fiscal year 1998 President's budget called for physicians to bill Medicare for their actual acquisition costs. The Congress rejected this proposal in favor of the modified AWP minus 5 percent standard. Among the methods for lowering excessive prices are a policy based on the principle of inherent reasonableness and the implementation of a single drug pricer (SDP).

CMS efforts to reform the payment system

The Congress first passed an inherent reasonableness provision in the Catastrophic Coverage Act of 1988. The provision required CMS, not the carriers, to institute a process for reducing payments for Medicare-covered items where payment rates were not inherently reasonable. In 1991, CMS was first allowed to use this process to adjust payments for medical equipment and supplies. It has only done so successfully once, for blood glucose monitors, a process which took almost three years.

The BBA allowed CMS to reduce payments for drugs if the formula price was not inherently reasonable. It created a streamlined inherent reasonableness process that allowed the agency to adjust payments up to 15 percent annually. In 1998, the agency tried to use this provision to lower the price of albuterol by 11 percent. This attempt generated considerable controversy as providers noted that CMS had not followed the customary regulatory process, including providing a full comment period before issuing a final rule. The Congress suspended use of the inherent reasonableness provision in the Balanced Budget Refinement Act of 1999.

A further attempt to reduce drug payments occurred in 2000. The Department of Justice and the National Association of Medicaid Fraud Control Units collected market wholesale prices for 49 drugs covered by Medicaid. CMS instructed Medicare carriers to use these prices as an additional source of AWP data in determining drug reimbursement updates for 2001. Carriers were instructed not to use the data for chemotherapy drugs and blood clotting factor. However, a provision in BIPA prevented the agency

from implementing this change pending release of a now-complete GAO study on Medicare drug pricing and related issues.

Following release of the GAO report, CMS continued efforts to reform the payment system, issuing an interim rule on inherent reasonableness on December 13, 2002. The rule states that if the payment system results in payments that are grossly deficient or excessive (more than 15 percent variation from market price) for an item or service, the agency can act to change the price. If the payment adjustment results in payment differences exceeding $100 million per year, CMS must publish its plans to adjust the fees in the Federal Register and allow a comment period of 60 days. Reductions cannot exceed 15 percent annually. The rule states that inherent reasonableness can be applied to drug prices.

On December 3, 2002, CMS announced the establishment of an SDP policy for drugs and biologicals covered under Medicare Part B. The new prices went into effect on January 1, 2003. The agency chose Medicare carrier Palmetto GBA to calculate AWPs for the program. Covered drugs will still be reimbursed at the rate of 95 percent of AWP and the carrier will continue to use current sources such as the Redbook and National Data Bank to determine AWPs. A CMS spokesperson estimated that the SDP will save the program about $50 million dollars annually because the chosen carrier "has a strong record for thoroughly researching prices" (Medicine and Health 2002). CMS estimates that beneficiaries could save between $10 and $30 million in lowered copayments (Coughlin 2002). Establishment of a single national price ensures that all providers will be paid at the same rate for identical products. Drugs provided in outpatient departments of hospitals under the outpatient prospective payment system or in conjunction with durable medical equipment are not affected by the new policy.[9]

In Congressional testimony, CMS administrator Tom Scully noted that choosing a single carrier to price covered Part B drugs would create the infrastructure for further changes. In time, the carrier could use market surveys to calculate AWPs based on what physicians and other purchasers pay for drugs. He estimated that this step could save $500 million annually.

Alternatives to the current system

Analysts have suggested a number of alternatives to the current AWP-based formula to pay for Medicare-covered drugs in a manner more consistent with market prices. The majority of the proposals involve two steps: First a benchmark price is chosen and then a payment method is developed based upon it. Additional approaches include: competitive bidding, basing payment on provider invoices, and empowering an independent commission to recommend updates to Medicare fees. Although all of these payment methods have the potential to reduce Medicare payments for Part B drugs, each must also be evaluated on the basis of a number of other dimensions including its: effect on beneficiary access, administrative costs entailed (for both the government and providers), and possible impact on the pharmaceutical marketplace. Since policy options will differ on these dimensions, policymakers must weigh the advantages and disadvantages of each approach. In addition, proposals may be more or less feasible for different types of drugs: Some payment alternatives may work better for single source than for multisource drugs and vice versa. In this section, we will outline a framework for analyzing these alternatives.

Evaluation criteria

- **Price.** How would a new payment system affect Medicare payments for drugs? Any new payment method would be expected to reduce Medicare payments to a level closer to the market price. However, proposals may have different effects for existing payments compared to those for products just entering the market. Further, the impact may differ on payments for generic drugs and multisource drugs compared to single source drugs.

- **Access.** Would changing payment methods affect beneficiary access? Research has concluded that some providers receive inadequate reimbursement for administration of covered drugs (see p. 157). For this reason, providers have argued that high drug reimbursement has been necessary to subsidize drug administration costs. They contend that changing drug payments without increasing administration rates would adversely affect beneficiary access.

  The following analysis does not attempt to measure inadequate fees for drug administration or dispensing services. MedPAC recognizes that changes in the drug payment method have implications for other parts of the payment system. Our analysis of drug payment alternatives assumes that payment changes for drug administration will be corrected separately through the appropriate payment systems.

  Any change in the payment system could also affect access by providing incentives for providers to move treatment from one site of care to another. Inappropriate changes in the site could affect the quality of care received by beneficiaries. It could also increase beneficiary and program expenditures by transferring services to a more expensive setting.

- **Administrative costs.** What sorts of administrative costs would the new system entail? Implementing a new payment system could increase administrative costs for both the Medicare program and providers. Costs could come in the form of

9 The durable medical equipment carriers already have a system in place to ensure a single price for each HCPCS drug code for the claims they process.

requirements for increased data collection and analysis, drug invoice processing, or in implementing and managing a new payment system.

- **Market effects.** How would the new payment system affect the pharmaceutical market? A new payment system has the potential to affect the way drugs are priced, marketed, and distributed. Currently, pricing information is regarded as proprietary information by pharmaceutical manufacturers. A Medicare payment system that resulted in price transparency could change the dynamics of the pharmaceutical marketplace, shifting the relative negotiating power of buyers and sellers. A payment method that required Medicare to receive the best price offered by manufacturers to any customer could result in higher prices for other public and private payers. Additionally, a system that requires changes in the way providers purchase drugs could create winners and losers in the pharmaceutical distribution market. Finally, a system that resulted in lower profits for drug manufacturers could lead to decreased investment in research and development. As a result, fewer new drugs might be developed.

In the following section, we analyze proposed new payment systems in terms of these dimensions, after briefly discussing each payment method. We focus on the areas of price, beneficiary access, administrative costs, and market effects. When appropriate, we will refine our analysis to reflect the potential effects of payment methods on different types of drugs. To avoid unnecessary repetition, we focus on those factors likely to be affected by the proposed method.

Payment system approaches

Multiple approaches could reform the way Medicare pays for covered drugs. The following list, culled from Congressional testimony, government reports, and other studies, is not exhaustive but includes a wide range of options that have been publicly discussed.

Some methods would result in a standard Medicare payment rate for each drug and others would increase payment variation. There are advantages to having one standard payment rate for each drug, particularly since the market for drugs is national. Because they would receive one predetermined fee, physicians would have an incentive to be prudent purchasers. They could keep any difference between what they paid for a drug and the Medicare payment. Over time, this might result in lower prices for the Medicare program and beneficiaries. On the other hand, in a competitive bidding model, payment variation could encourage competition among suppliers, leading to lower prices. Payment based on invoice prices also would increase payment variation. It would reduce incentives for prudent purchasing and could lead to higher prices. However, some physicians might have trouble purchasing drugs at a standard Medicare payment rate, particularly if they are in small practices. For them, payment variation would ensure access to drug supplies.

Benchmarking methods

AWP-based method Medicare could continue to use AWP as a benchmark price but change the payment formula to require a steeper discount. The Congressional Budget Office (CBO) has suggested that Medicare could reduce its payments for Part B drugs to 85 percent of AWP (CBO 2003). The proposal would also limit annual increases in the allowed charges for covered drugs to changes in the consumer price index.

This method would lower the price Medicare pays for existing covered drugs but, as CBO noted, might provide some incentive for manufacturers to price new drugs at AWPs higher than might otherwise be the case. As in the current system, providers would have the incentive to switch from an existing drug to an equally effective new drug priced with a higher AWP to maximize their profit. In recent years, there has been rapid diffusion of new covered drugs under Part B. As our research indicates, we expect this trend to continue, making the launch price[10] problem an important consideration.

In addition, the effect of the payment change on existing drugs would be uneven. For many multisource or generic drugs, the additional discount would still result in payments substantially higher than acquisition costs. However, some providers might have difficulty acquiring less heavily discounted innovative drugs at the new rate. Further, as within the current payment method, AWP would not correspond to any transaction prices and could not be audited.

In general, this proposal should have a very limited effect on beneficiary access to drugs. Providers would still profit from differences between the list price of a drug and their acquisition costs. If the new system substantially changes incentives for different types of drugs, prescribing patterns could be affected. For example, providers might have an incentive to use new drugs introduced with high AWPs marketed at discounted rates, regardless of whether the new drug was more effective or offered other health benefits. For new drugs, beneficiary cost sharing would increase since they would be responsible for 20 percent of a higher price. On the other hand, for older drugs, beneficiaries would pay 20 percent of a *reduced* price. The overall effect is unclear. The payment method would not change the incentives for manufacturers to market their products on the basis of the spread between AWP and provider acquisition costs.[11]

10 A launch price is the price a manufacturer gives to a new drug when it is first marketed.

11 However, it is possible that OIG guidelines might eliminate this practice (see p. 157).

This method would not substantially increase administrative costs for CMS or providers. The potential effect on the market would be to increase the launch price of new drugs. Distribution channels for covered drugs should not be affected.

Another method that continues the use of AWP as a benchmark would be to maintain the present payment method but change the way CMS calculates AWP. As noted previously, no method for calculating AWPs exists in law or regulations. The agency could conduct a survey of market prices for covered drugs and use the resulting averages as their benchmark measure of the AWP. Information could be based on wholesalers and group purchasing organization catalogues or surveys of private health plans and physicians. In testimony before the House Ways and Means Committee in October 2002, CMS administrator Tom Scully stated that the agency would take this approach in the absence of Congressional action.

Implementing this method should result in lower prices, especially for generic drugs, without affecting access to needed therapies. A need for ongoing market surveys to obtain pricing information would entail additional administrative costs for CMS or its contractors.

This payment system could affect the pharmaceutical market if manufacturers limit the publicly available discounts from AWP and substituted additional rebates and private discounts for their best customers. These rebates would not be captured in market surveys. In the MedPAC survey of private payer methods, one informant suggested that manufacturers were already taking this approach. If manufacturers tie rebates to increasing the market share of their products, it could affect pharmaceutical prescribing patterns. The result would be a wider variation in prices available to providers to purchase covered drugs, and providers with lower market shares paying higher prices.

Methods based on alternative benchmarks Medicare could base its payment method on a computed average transaction price such as the average manufacturer price (AMP), the average sales price (ASP), or the average acquisition price (AAP). The AMP is the computed average price paid by wholesalers to manufacturers after accounting for discounts for a particular dosage, form, and strength of a drug distributed through retail outlets. Manufacturers calculate and submit this figure to CMS to determine the rebate owed by manufacturers to Medicaid. The figure is not publicly available. Manufacturers could use the same method to calculate the ASP or AAP to capture transaction prices beyond drugs distributed through the retail level. Together, they represent the weighted average of all final sales prices charged for a product in the United States, excluding products exempt from calculations for the Medicaid best price.[12] All rebates and discounts are included in the calculation. Proposals would pay providers a specified percentage above the benchmark price. Although proposals differ as to how high to set the additional payment, the goal is to ensure that all providers will be reimbursed for their acquisition costs.

This proposal would reduce payment levels for Medicare-covered drugs. Estimated savings would depend upon the percentage Medicare paid above the benchmark price. Providers would be paid based on an average transaction price, but some would pay higher than average prices for drugs. The Medicare payment rates would have to be set above the benchmark to accommodate those purchasers. Savings would likely differ by type of drug. Currently, a large difference exists between listed AWPs and provider costs for generic drugs. Under a payment system based on these benchmarks, Medicare payments for generic drugs would be reduced to sums closer to actual market prices. The gap between AWP and provider purchase price is narrower for most brand name drugs that do not face competition. Before enacting a payment method based on this approach, policymakers should ensure that the payment rate is set high enough to meet provider purchase costs but not so high as to increase Medicare payments for these drugs. Payment rates could be set differently for generic and single source drugs.

In general, payment systems based upon these benchmarks should not affect access to covered drugs because the payment rate would have to be set high enough to cover acquisition costs for providers.

Administrative costs to implement this system would be modest. Manufacturers already compute average prices for their products and submit them to the Medicaid program, although the OIG (1998) has identified inconsistencies in the present methods used by manufacturers to calculate the AMP. Calculation of some of these benchmarks would require that manufacturers include more pricing information in the measures than they currently do for Medicaid. The data collection process would not change much, except to address coding issues. Because manufacturers calculate average prices for their products in terms of individual NDCs (see p. 154) while Medicare pays on the basis of HCPCS codes, CMS would have to create a process to translate NDC prices into the appropriate Medicare codes.[13] HHS also would require some additional resources for an auditing system to ensure the integrity of the data.

Using AMP, ASP, or AAP could have an impact on the pharmaceutical marketplace by lessening manufacturers' ability to charge different prices to different purchasers. Although customers would not know exactly what amount other purchasers negotiated with manufacturers, they would know the average price embedded in the fee schedule. Purchasers would be reluctant to pay above that level.

12 Determinations of which prices should be excluded from calculations of the ASP have varied in different discussions of this method.

13 This would also be necessary if the benchmarks used were FSS prices.

One result might be that manufacturers would reduce the size of the discounts they offered their best customers (i.e., raise prices) to prevent reductions in their average price. When the Medicaid rebate program was implemented, manufacturers reduced the size of discounts they offered their best customers to limit the size of the rebates they owed to the Medicaid program (CBO 1996). This would have a negative impact on the Department of Veterans Affairs (VA) and other users of the federal supply schedule (FSS) entitled to the lowest privately contracted price for any drug.

Another way to create a new benchmark would be for Medicare to base its payments on the FSS prices (Grob 2001). Generally, under the FSS the price for a drug may not be higher than the lowest contracted price paid to a manufacturer by any nonfederal purchaser.

Because providers, in general, could not purchase covered drugs at FSS prices, Medicare payments would be based on a percentage level above the FSS price. Potential savings would depend upon the designated amount. The proposal would be expected to have the same impact on access as detailed for other benchmarking proposals. That is, if the amount is above acquisition costs, it should not affect access. Administrative burdens would be modest since FSS prices are publicly available.

As with other benchmarking approaches, this payment method could affect dynamics in the pharmaceutical marketplace. Since FSS prices are based on the lowest contracted price paid by any private purchaser, manufacturers might raise prices to private purchasers to avoid having to offer their products for the designated percentage above that price to all Medicare beneficiaries.

Payment based on invoice prices Medicare could require providers to submit invoices for drug purchases to receive reimbursement. Medicare payments would be based upon these prices. The invoice price likely would not take into account later rebates and discounts offered on the basis of volume purchases or changes in market share.

It is unclear what effect this method would have on prices. It would tend to increase variation in Medicare payments for drugs compared to the previously described methods. In general, drugs would no longer be marketed on the basis of the difference between the AWP and provider acquisition costs. Providers that were paid their costs would have no reason to be prudent purchasers; the result could be higher prices. On the other hand, as in the method of using market surveys to determine AWP, manufacturers might limit public discounts from AWP and substitute additional rebates and discounts for their best customers. Those with less market power would pay higher prices. Providers could maximize their purchase of particular therapies if manufacturers tie rebates to increasing the market share of their products.

Administrative burden would increase for both providers and CMS if each must submit and process invoices. For the agency, in particular, payment for each drug claim would need to be calculated individually.[14]

Competitive bidding method Under this approach, designated entities compete to supply Part B drugs to beneficiaries or their physicians. Under one variant, durable medical equipment (DME) suppliers could submit bids to cover the cost of providing drugs used with inhalant or infusion therapy to beneficiaries. CMS tested this alternative in the San Antonio DME competitive bidding demonstration project. In this project, pharmacy suppliers bid for albuterol, a drug used with nebulizers for respiratory illnesses. Medicare saved 20 percent over what it would have paid without competitive bidding, with no discernable decline in access for beneficiaries.[15] (See Chapter 8 for a detailed analysis.)

Administrative costs for the demonstration were high, but savings clearly outweighed them. Costs included educating providers on the bidding process, collecting and analyzing bids, and hiring a full-time ombudsman to monitor beneficiary access to products. It is expected that these costs relative to savings would be lower once the infrastructure for the bidding process is in place and overhead costs are spread across more areas.

A system of competitive bidding by pharmacy suppliers for drugs dispensed with durable medical equipment should not initially affect the operation of the pharmaceutical marketplace, because drugs used in this sector tend to be generic, and multisource drugs are available from multiple manufacturers. Suppliers already have purchasing practices for these items in place. Similarly, beneficiaries currently purchase these drugs through pharmacy suppliers. Although the number of suppliers would be reduced, the system should be designed to ensure that enough successful bidders participate to maintain beneficiary access. Additional suppliers could bid in subsequent rounds. However, if the number of bidders accepted is too low, this method could result in fewer suppliers and reduce the competitiveness of a market over time.

A system of competitive bidding for physician-administered drugs would require a different structure. One variant on this approach would be the preferred supplier. Under this system, suppliers such as group purchasing organizations, pharmacy benefit managers (PBMs), specialty pharmacies, or retail pharmacies could bid to provide physician-administered drugs to the Medicare program at a set price. Physicians would purchase drugs from the successful bidders. They would be free to choose the supplier of their choice among the winning bidders and would bill Medicare for the drugs. Medicare payment would be

14 There may be some administratively less burdensome methods to implement a payment system based on invoice prices.

15 As noted on p. 156, GAO found that widely available discounts for albuterol averaged 85 percent below AWP.

based on the average successful bid. In some variants, physicians could purchase from other suppliers as well but would receive lower Medicare payments.

A second method,[16] currently being tested by some private purchasers, takes physicians out of the process of purchasing drugs and billing Medicare. It requires Medicare-designated plans or other entities like specialty pharmacies or PBMs to negotiate with manufacturers over prices for their covered products. Physicians order drugs as needed and the designated entity bills Medicare directly for the product at the negotiated price. This method eliminates any incentive for manufacturers to increase the spread between Medicare payments and physician purchase prices.

Policymakers would have to address certain design issues. The system would have to minimize disruption to physician procurement practices. In the case of chemotherapy, physicians have to prepare drugs for individual patients on the day of administration. Planned courses of medication change depending upon the patient's condition and physicians have to maintain inventories sufficient to handle these changes. In the selective contracting model, physicians have to order drugs in advance. Last minute changes could only be accommodated through inventory on hand. Although the supplier could then replace the drugs, physicians could object to having the risk of maintaining an inventory that might not be used and could not be billed to Medicare.

The selective contracting model should result in lower Medicare payments for generic drugs and brand name drugs with therapeutic equivalents. However, it might not achieve much savings for innovative brand name drugs because there is little variation in the prices charged by manufacturers for these drugs. This raises as a question whether payment methods should vary by type of drug.

Method based on commission-recommended updates In Congressional testimony, the OIG (Grob 2001) suggested that one possible way to reform the payment system would be to charge an independent commission with the task of recommending updates to Medicare fees for covered drugs. Using a method analogous to the framework used by MedPAC, the commission could judge the adequacy of current drug payments and consider factors affecting future costs before recommending changes for the upcoming year. However, more detail would be necessary to analyze this approach according to the framework developed here.

Although every approach analyzed here has advantages and disadvantages, each option, if carefully constructed, has the potential for a significant improvement over the current payment system. All methods eliminate the current incentive for manufacturers to raise the AWP of a product in response to competition, but those based on AWP or invoice prices could lead to lower public discounts and wider use of rebates and discounts for best customers. The analysis suggests that it might be appropriate to vary payment methods by drug types, for example, depending upon whether the drug is a single source brand name or generic, or an innovative product compared to one with therapeutic equivalents.

Lessons from other payers

Analysis of payment methods used by other public and private payers may provide lessons helpful for reform of the current system. Public programs like Medicaid and the VA may provide insights into reform of the Medicare payment system. Little is known about how drugs like those covered by Medicare are distributed and paid for in the competitive private market. MedPAC surveyed large private payers on their current payment rates for physician-administered drugs and any plans they have to change their payment formulas. Most private payers are still using AWP-based payment methods similar to the Medicare model. Increasingly, however, rising expenditures are leading them to consider different strategies. We will explore some of the new developments in the pharmacy distribution market that relate to these drugs to see what implications they may have for Medicare payment policy.

Public programs

The Medicaid program and the VA designed payment systems to reduce drug expenditures for both programs. Medicaid as a third-party payer for drugs purchased by others relies on payment formulas to determine reimbursement rates. The VA, both because of statutory provisions and because it operates within an integrated delivery system, is able to negotiate particularly low prices for use in its own facilities.

Medicaid's payment system for drugs is very complex. It has two elements: payments made at the point of sale and rebates returned to the program from pharmaceutical manufacturers. At the point of sale, each state determines its own payment rates within certain federal guidelines. In most cases, Medicaid reimburses pharmacies using discounted AWP prices plus a dispensing fee.

Manufacturers who want Medicaid to cover their products must submit information to CMS on both the average manufacturer price (AMP) and the best price offered to private payers. The AMP is a computed average price paid by wholesalers to manufacturers after accounting for discounts for a particular dosage, form, and strength of a drug distributed through retail outlets. To receive rebates, states inform manufacturers of the number of units of each drug they paid for and the payment totals for each NDC. States then receive

16 A number of different terms have been used to characterize this method including selective contracting, stock replacement method, and mandatory acquisition method.

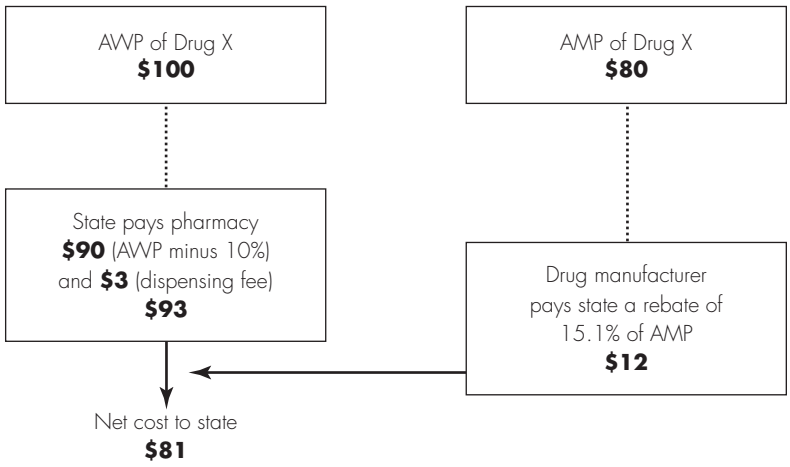
manufacturer rebates equal to the greater of 15.1 or 11.1 percent off the AMP for single source drugs and multisource or generic drugs, respectively, or the difference between the AMP and the best price.[17] The rebate formula also requires an additional payment if drug prices rise faster than the consumer price index. Since the retail price paid by the states will be greater than the AMP, Medicaid prices do not equal the lowest price paid to any customer. Figure 9-5 illustrates this process.

While this formula applies to drugs provided through pharmacy suppliers and home health agencies, states have generally not received rebates on drugs administered incident to a physician's services. Physician-administered drugs are usually paid through the state-established physician fee schedule, in a process like Medicare's payment system. Recently, CMS issued a program memorandum instructing states to collect data on physician-administered drugs in order to obtain rebates.

Prices paid by the VA are affected by various factors. The VA administers the federal supply schedule (FSS), a list of prices for drugs available for federal purchasers. Since passage of the Veteran's Health Care Act of 1992, manufacturers must make drugs available to specified public purchasers at the FSS price to have their products covered by Medicaid. The schedule is based on market transactions reported by the manufacturers and may not be higher than the lowest price provided to private payers for outpatient drugs in the domestic market. In addition, manufacturers must sell brand name drugs to the VA, the Department of Defense, the Public Health Service, and the Coast Guard at prices at least 24 percent below the AMP.

The VA uses competition to further lower the prices it pays for drugs dispensed within in its own facilities. For certain therapeutic classes, physicians within the system create lists of therapeutic equivalents or drugs that can be used interchangeably to treat the same condition. Administrators then use these lists to create closed formularies offering access to only a few drugs within a class. Manufacturers that offer the lowest price can get their product listed on the formulary.

FIGURE 9-5 **Medicaid drug reimbursement example**



Assumptions:
- The state's Medicaid reimbursement formula is AWP minus 10 percent.
- The state does not have a "usual or customary" standard for drug reimbursement.
- The state pays a dispensing fee of $3.00.
- The difference between the drug's AMP and the manufacturer's "best price" is not greater than 15.1 percent of the drug's AMP.
- The drug is not a generic, which would have a rebate of 11 percent of AMP.

Note: AMP (average manufacturer price), AWP (average wholesale price).

Source: Gencarelli D. Average wholesale price for prescription drugs: Is there a more appropriate pricing mechanism? Issue brief No. 775, National Health Policy Forum. 2002.

Private payers and specialty drugs

In describing trends in the private market, this section focuses on physician-billed drugs and other high-cost injectables because they represent the most rapidly growing portion of the public and private pharmaceutical market. This rapid growth has prompted insurers, health plans, specialty pharmacy companies, PBMs, and retail pharmacies to explore new ways to monitor and control expenditures without impeding access to needed medications by patients. The results of the survey of health plans presented below show implementation of these new payment methods is still in an early stage, and it is too soon to evaluate the success of these models.

Physician-administered drugs are often grouped with a class of medications known as specialty drugs. The specialty drug category typically includes injectable drugs, infusible drugs, biotechnology drugs, and other medications administered in a physician's office. One of the major differences between Part B drugs and the types of medications classified as specialty drugs in the private market is that a much greater percentage of private injectables are self-administered and delivered by pharmacies directly to the patient's home. Medicare coverage rules generally require Medicare to cover only those injectables that are not usually self-administered.

17 Both the AMP and "best price" are confidential.

Specialty drugs treat life-threatening and chronic conditions such as cancer, HIV/AIDS, hemophilia, hepatitis C, multiple sclerosis, rheumatoid arthritis, and anemia. Medications for these conditions are distinguished by their high cost ($5,000 to $250,000 per patient per year)[18] and the complex care required for their preparation, delivery, administration, and continuing patient care. For example, many of these drugs must be individually prepared based upon the patient's weight and the physician's dosage instructions. Each unit dose is prepared separately and must be kept refrigerated and shipped quickly to prevent spoilage. As these products are expensive, many insurers require providers to obtain prior authorization before dispensing them. Since drug regimens within these disease categories are often characterized by serious drug interactions and unpleasant side effects, patients require frequent monitoring to prevent adverse reactions and to ensure that patients continue taking their medications as prescribed.

IMS Health, a large pharmaceutical market research and consulting firm, estimates that purchasers spent $19 billion on specialty drugs in 2001, an increase of 24 percent from 2000. These drugs represent about 11 percent of the United States pharmaceutical market[19] and are its fastest growing sector. One analyst estimates that the use of injectables alone has doubled over the last five years (Tercero 2002).

How do private payers determine payment rates for physician-administered drugs?

Until recently, private payers devoted little attention to price and utilization of specialty drugs. Their payment systems, and the problems associated with them, have mirrored Medicare's AWP-based formula. These drugs are most often administered through a health plan's major medical benefit rather than as part of the pharmacy benefit.[20] When billing drugs through the major medical benefit, physicians purchase needed drugs and submit claims to their patient's insurance plan along with other claims for services. Any discounts or rebates that the physicians receive for drug purchases are not passed on to the plan.

This system also makes it difficult to screen for interactions between drugs administered by different physicians or additional outpatient drugs taken by the patient. The J-codes used by Medicare and most private payers to pay claims for physician-administered drugs can limit the effectiveness of all utilization management techniques. Because they are aggregated across several NDC codes, they mask important information needed to manage utilization. Their use limits the insurer's ability to examine physicians' prescribing patterns and to make sure they are providing or paying for the amount of a drug that the patient uses. Further, many physician-administered drugs are newly approved products, and there can be significant delay in the assignment of a J-code after FDA approval. In the interim, claims for such drugs use a miscellaneous J-code that further inhibits the ability of an insurer to manage the benefit.

Analysts argue that the multiple definitions, multiple claims administration processes, and the difficulty providers have in classifying drugs of this type have created barriers to effective management.

Survey results

In conjunction with a MedPAC-sponsored survey of health plans on their physician payment rates, Dyckman et al. (2002) surveyed 32 health plans on their pricing formula for physician-administered drugs (Table 9-2). They also asked respondents about anticipated changes in their pricing methods. Surveyed plans had a combined commercial enrollment of 45 million covered lives. Plans included Blue Cross Blue Shield plans and national managed care health insurance companies.

Findings from the survey include:

- All plans reported pricing formulas based upon the AWP but at least 13 plans use different pricing strategies for different categories of drugs or providers.
- Eight plans have entered into selective contracting, or prescribed distribution channel agreements, with pharmacy providers for at least some therapeutic classes. Plans sometimes noted that the pricing formula differed for products purchased for physicians through specialty pharmacies.
- Some of the plans used varying percentages of AWP for different categories of drugs, such as medications for chemotherapy, immunization, and vaccines.[21] Of those plans specifying different pricing formulas for chemotherapy drugs, four paid a lower percentage of AWP for these drugs than for other types, and three paid at a higher rate than for other drug categories.
- There was considerable variation in the frequency with which plans updated AWPs.

Plan respondents were aware that physicians typically purchased drugs at prices well below AWP and that the payment methods resulted in additional profits for physicians. About one-half of the plans considering changing their payment methods for drugs noted that they might have to raise physician administration fees to partially offset the reduced income generated for physicians.

18 One large PBM estimates that the average injectable drug costs more than $1,000 dollars per month (Express Scripts 2003).

19 Because of the lack of precision in the definition of specialty drugs, estimates of total expenditures differ considerably by source.

20 One source estimates that injectable drugs are covered under the major medical benefit about two-thirds of the time (Atlantic Information Services 2002).

21 When pricing formulas differed by category of drugs, the researchers reported the formula used for pricing of chemotherapy drugs.

TABLE 9-2

Health plans' pricing for physician-administered drugs, by AWP formula

	85–90% of AWP	95% of AWP	100% of AWP	101–109% of AWP	110–115% of AWP	Health plans responding
Number of plans	7	8	10	5	2	32
Percent of plans	22%	25%	31%	16%	6%	100%

Note: AWP (average wholesale price).

Source: Dyckman and Associates, memorandum. December 22, 2002.

At least nine of the responding plans reported that they were changing or evaluating their payment method for physician-administered drugs in 2003. They cited a variety of strategies including: changing the payment formula to a lower percentage of the AWP; reducing prices based on actual market prices or acquisition prices for drugs; implementing group purchasing programs to enable physicians to purchase drugs at competitive prices (and lowering the amount paid to physicians who purchased outside of the contracted arrangement); and contracting with specialty pharmacy vendors who could supply physicians with needed drugs at reduced prices. In some cases, anticipated changes in payment formulas were limited to specific categories of drugs.

What new methods are being employed by payers?

As reflected in the range of options being considered by plan respondents, the market for providing specialty drugs is still evolving and has been characterized in recent years by mergers, purchases, and strategic partnerships. Specialty pharmacies, PBMs, and health plans, working individually or in concert, are developing diverse methods for the payment and delivery of these drugs. Some retail pharmacies also have developed specialty pharmacy subsidiaries. Only as expenditures sharply increased in the past few years have payers begun to focus on more efficient methods for paying for these drugs and managing utilization. As payers implement changes, they tend to focus on the characteristics of specific diseases or therapies.

MedPAC contracted with researchers at NORC at the University of Chicago and Georgetown University (NORC/Georgetown 2003b) to conduct a series of structured interviews with physicians, payers, specialty pharmacies, and PBMs for further insight into how these new payment methods work in practice. The study emphasized, but was not limited to, channels of distribution and payment for chemotherapy drugs. Informants discussed the traditional acquisition and payment system as well as new methods. While health plans, specialty pharmacies, and PBMs were generally positive about potential benefits from the new payment methods, physicians expressed significant concerns about both the clinical and financial implications of most of the innovations being adopted by private payers.

Specialty pharmacy and pharmacy benefit managers

Specialty pharmacies developed as niche providers, specializing in providing drugs for one or a small number of serious medical conditions. Currently, about $7 billion, or 30 percent of all specialty drugs dispensed in the United States, are distributed through specialty pharmacies (Ransom 2002). They are generally mail-order facilities without retail settings. The pharmacies are distinguished by their expertise with the preparation, management, and delivery of all therapies associated with a particular disease. Among the additional services offered are compliance programs to assure that providers will be reimbursed for dispensed products, and 24-hour patient assistance programs to address patient concerns and ensure that drugs are taken as prescribed.

Some specialty pharmacies have developed disease management programs to assist patients with serious chronic conditions in maintaining their therapeutic regimens. They also provide informational services to pharmaceutical manufacturers in the form of detailed nonpatient specific information on treatment trends and patient outcomes within disease categories (Ransom 2002). Some specialty pharmacies develop special business relationships with particular manufacturers. For example, Biogen, the manufacturer of the multiple sclerosis drug Avonex, has a preferred mail-order agreement with one specialty pharmacy.

While proponents of the specialty pharmacy model argue that these entities are able to negotiate lower prices with manufacturers and achieve higher rates of patient compliance, others believe that the special relationship between the pharmacies and manufacturers creates the potential for conflict of interest. In addition, because the specialty pharmacies focus on specific diseases, they may be unable to monitor for interactions between drugs taken for different conditions. However, some larger specialty pharmacy companies provide services for an increasing number of diseases.

Most large pharmacy benefit managers (PBMs) have created their own specialty pharmacy units or purchased existing specialty pharmacies. They differ from the traditional specialty pharmacy in three ways: They provide integrated management programs that achieve efficiencies in claims processing and cost reporting, track all drug usage and develop programs to prevent adverse drug interactions, and apply tools developed for

outpatient drugs within the injectable drug setting. For example, PBMs use techniques such as prior authorization and preferred drug lists to control drug utilization and expenditures. Utilization management offers payers the potential to reduce costs by identifying clinically inappropriate uses of physician-administered drugs. This type of management is common for self-administered drugs but has not been used much for physician-administered drugs. PBMs can provide the opportunity to examine utilization, especially if they use NDC codes that capture size and strength of dispensed drugs. Although it does not create closed formularies in this setting, one PBM establishes pharmacy and therapeutics (P&T) committees to determine therapeutic equivalents using evidence-based research. These determinations can be used to negotiate lower prices with manufacturers (Tercero 2002). However, critics contend that P&T committees may not have the expertise to evaluate biotechnology drugs and that their focus on utilization management may keep individual patients from receiving the most appropriate drug for their particular condition (AIS/PharMedQuest 2001).

Health Plans

As noted in the survey results reported above, most health plans are only beginning to address payment issues for specialty drugs. Some have contracted with specialty pharmacies or PBMs for management of particular categories of drugs. Others have created their own in-house specialty pharmacy to meet their needs.

One large health plan created a specialty pharmacy network (SPN) and has contracted with individual specialty pharmacies for purchase and management of drugs for specific conditions. Each of the contracted providers specializes in a particular disease. Members of the SPN distribute drugs directly to physicians and patients, and bill the health plan. They also provide patient education and disease management services in some cases (Atlantic Information Services 2002).

New acquisition methods and chemotherapy

In comparison to other specialty areas, relatively few private payers have implemented selective contracting methods for chemotherapy-related drugs (NORC/Georgetown 2003b). One difference is that the administration of oncology drugs involves a greater number of ongoing clinical decisions, with frequent changes in drugs and dosages based on how the patient responds. Physicians need to have sufficient inventory[22] on hand to be able to change therapies based upon a patient's condition on the day of chemotherapy administration. Physicians also object to losing the ability to have one organization handle all their drug transactions, as is typically the case under traditional arrangements. Several note concerns about the quality of drugs received from unknown suppliers. They also indicate problems stemming from the need to keep track of multiple insurers and maintain multiple inventories.

The ability of insurers to get physicians to accept the new payment methods appears to depend upon the relative clout of physicians and insurers in a particular market. In one case, physicians closed down their office-based practices for three months in response to new payment methods and shifted treatment to hospital outpatient departments. This raised the cost of a chemotherapy session from $3,000 to $5,000. At least one respondent noted that resistance can be overcome, but it requires considerable effort and outreach. Several respondents noted that, among different parties, oncologists have the greatest leverage in these disputes.

Because of these difficulties, many insurers have chosen not to become involved in the distribution channel but have lowered the amounts they are willing to pay oncologists for the drugs they use in their offices. Many of them raised administration fees at the same time.

Impact of new payment methods

Interviewees cited two sources of potential cost savings—reduced prices for drugs, and, to a lesser extent, savings achieved through utilization management. Interviewees agreed that the prescribed distribution channels and new payment levels do yield lower per unit prices, but few were willing to provide data on savings. One PBM noted that it worked with a medical group that was given the option of using a prescribed distribution channel or accepting a payment level equal to what the PBM could achieve if it purchased the drugs. They estimated that, under this system, they achieved an average savings of 14.1 percent below AWP. Another company reported experiencing savings in the range of 10 to 25 percent by lowering payment levels, especially for nononcology drugs. No interviewee could quantify the savings realized through utilization management of cancer drugs. Many of the new payment methods are still pilot projects and results are as yet unavailable. ■

22 Two respondents reported that their large group practices might keep an inventory worth $300,000 to $500,000 on hand, about a week's worth of medication. These larger practices have a regular volume of patients that necessitates having a good supply to accommodate changes in treatment on the day the patient comes to the office. Certain drugs are not used often but may be needed urgently on short notice (NORC/Georgetown 2003b).

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