JANUARY 2007

REPORT TO THE CONGRESS

Impact of Changes in Medicare Payments for Part B Drugs

MEDPAC Medicare Payment Advisory Commission

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Executive summary

Executive summary

In 2005, Medicare implemented significant changes in the way it pays physicians for physician-administered drugs and drug administration services. The Congress mandated that the Commission conduct two studies to review the payment changes to see if they affect quality of care and satisfaction of patients, have differing effects on the adequacy of payments in different geographic regions and different physician practice sizes, and have an impact on physician practices. Our first report, relating specifically to oncology, found that Medicare obtained savings on oncology drugs and the volume of oncology services increased. Beneficiaries continued to have access to chemotherapy services, although beneficiaries without supplemental insurance are more likely than other beneficiaries to receive chemotherapy in hospital outpatient departments. In addition, physicians reorganized their practices to become more efficient and control costs by obtaining lower prices on drugs.

For this report, we focused on the experiences of urologists, rheumatologists, and specialists in treating infectious diseases. We also updated findings from our earlier report on oncologists. We found that the movement to a payment method based on average sales price (ASP) resulted in substantial price savings for Medicare on nearly all drugs. While the overall volume of claims for Part B drugs increased in 2005, urologists and infectious disease specialists provided fewer physician-administered drugs in their offices in 2005 than in 2004.

We found that physicians' reaction to the payment changes varied by specialty but all practices made at least some changes to lower their expenses, particularly their drug and staffing costs. As expected, large practices were better able to adapt to the payment changes than smaller practices.

Beneficiaries continue to have access to physician-administered drugs and we saw no indication that quality of care was affected, but measures to assess quality of care are inadequate.

MedPAC analyzed the effects of the payment changes on the provision of Part B drugs through a series of studies.

- We analyzed expenditures and changes in volume of Part B drugs and other services using Medicare claims data.
- We interviewed physicians, hospital outpatient departments, and health plans in seven markets to discuss the effects of payment changes on practices.
- We interviewed case managers at a large national patient assistance foundation to see what issues Medicare beneficiaries were reporting in relation to physician-administered drugs.

- We interviewed stakeholders to gain their perspective on how payment changes affected the buying and selling of physician-administered drugs.
- We reviewed the literature on pricing for Part B drugs and studies of indicators of quality of care for designated specialties.

How did the payment changes affect Medicare payments?

The change to an ASP-based payment system for Part B drugs affected expenditures for urologists, rheumatologists, infectious disease specialists, and medical oncologists. These specialties differ in terms of the volume of physician-administered drugs they provide and the proportion of their Medicare billing that is derived from drugs. Yet, in all cases, we saw a similar pattern. From 2004 to 2005 when the payment rate changed to 106 percent of ASP, total charges for each specialty (including drugs, drug administration, evaluation and management visits, tests, and other procedures) increased but spending on drugs decreased. The decline in expenditures for drugs ranged from 1 percent for rheumatology to 52 percent for urology. Much of the reduction in spending for drugs is attributable to lower prices. That is, ASP resulted in substantial price savings for Medicare on nearly all drugs and those payment rate changes drove decreased spending. Overall, total Part B drug spending (taking into account price and volume changes) fell from $10.9 billion in 2004 to $10.1 billion in 2005.

How did the payment changes affect quality of care and beneficiary satisfaction?

We have limited ability to assess the quality of drug administration services received by Medicare beneficiaries. There are few consensus quality indicators, although the specialty societies are working to develop more measures. Case managers at a national patient assistance foundation found that most beneficiaries who contacted them were concerned about costs rather than the quality of care they received.

How did the payment changes affect adequacy of payment and availability of services in different geographic areas?

Overall trends in spending for physician-administered drugs and drug administration services were similar in all geographic areas. Use of drug treatments for advanced prostate cancer declined most rapidly in areas that had the highest per capita use of these drugs before the payment change. MedPAC found no evidence of access problems for Medicare beneficiaries in any part of the country who needed physician-administered drugs. However, in some areas, beneficiaries without supplemental coverage may be more likely than other beneficiaries to receive chemotherapy in hospital outpatient departments rather than physician offices.

How did the payment changes affect adequacy of payment and availability of physician-administered drugs in different practice sizes?

We were unable to collect empirical data on this subject. Interviewees consistently told us that large practices were better able to adapt to the payment changes than smaller practices. Generally, larger practices were better able to negotiate lower drug prices. In addition, they were able to achieve economies of scale in their practices.

What was the impact on physician practices?

Our interviews suggest that physician practices considered the 2005 payment changes significant and that they made changes in response to the new payment system. Physicians responded to the changes by cutting costs and increasing efficiency (particularly with respect to drug purchasing activities), finding new sources of revenue (e.g., imaging), and selecting more profitable patients. Urologists made the most significant changes to their clinical practice, providing drug treatments to fewer Medicare beneficiaries. The decrease can be attributed to changes in practice patterns, greater awareness of drug side effects, and changes in the Medicare payment rate. Declines were greatest in those practices that had been providing the largest volume of drugs. We saw fewer changes in the clinical practices of rheumatology and infectious disease specialists.

Some manufacturers offer provider discounts for one of their products contingent on purchase of one or more other products. The way manufacturers allocate these bundled discounts in calculating ASP can affect the accuracy of the payment methodology.

The Commission recommends a policy change to improve the payment system and promote beneficiary access.

RECOMMENDATION:

The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.

The Commission also believes it is important for the Secretary to continue to monitor providers' acquisition costs to ensure that they are able to purchase necessary drugs at the payment rate.

Impact of changes in Medicare payments for Part B drugs

RECOMMENDATION

The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Part B drugs and physician practices

Before 2006, Medicare covered few outpatient drugs, and those covered under Part B were used to treat patients with serious medical conditions like cancer, hemophilia, and rheumatoid arthritis. Medicare expenditures for Part B drugs grew rapidly, rising from $2.8 billion in 1997 to $10.3 billion in 2003. Policymakers agreed that payment rates for Part B drugs were too high but providers argued that high rates were necessary to offset drug administration fees that were lower than the cost of administering them.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare pays for drugs and drug administration services under the physician fee schedule. As intended by the policy, payment rates for drugs were reduced to levels closer to provider purchase prices and payment rates for drug administration increased. Since 2005, physicians who provide Part B drugs to their patients have been reimbursed at the rate of 106 percent of the average sales price (ASP). As a result of the payment changes, Medicare spending for Part B drugs declined in 2005 despite increases in the volume of drugs used and the substitution of newer drugs for older, less expensive products.

The Congress directed the Commission to study the effect of these changes on beneficiary access and quality of care. Our first report, completed January 2006, focused on services provided by oncologists. We found that beneficiary access to chemotherapy drugs remained good, and we found no evidence that quality of care declined. However, beneficiaries without supplemental insurance and beneficiaries who are dually eligible for Medicare and Medicaid were likely to have more limited choices about where they received chemotherapy. Some offices shifted these patients to hospital outpatient departments for treatment.

In this report, we are studying the effects of the payment changes on drug administration services provided by urologists, rheumatologists, and infectious disease specialists. These specialties provide physician-administered drugs in their offices, although none provided the same quantity of drugs or derived as large a share of Medicare revenue from administering drugs as oncologists.

MedPAC analyses

The Commission undertook a series of quantitative and qualitative analyses to examine the effects of Medicare payment changes on the provision of physician-administered drugs to Medicare beneficiaries.

- We used Medicare claims data to analyze expenditures and changes in volume of Part B drugs provided to beneficiaries in selected specialties. We also examined changes in use of these drugs in hospital outpatient settings.
- With a research team from the National Opinion Research Center (NORC) at the University of Chicago and Georgetown University, we conducted structured interviews with urologists, rheumatologists, infectious disease specialists, oncologists, and hospital outpatient

departments from seven markets. We interviewed many physicians and managers from the same practices for the third consecutive year to monitor continuing changes.

- We met with case managers from the National Patient Advocate Foundation, a large nonprofit foundation that provides financial support and counseling to individuals with high medical costs. They discussed the kinds of issues reported by Medicare beneficiaries who need physician-administered drugs and trends in the number of beneficiaries needing assistance.
- We compared Medicare and beneficiary payments in physicians' offices with costs in hospital outpatient departments for specific drug regimens.
- We interviewed stakeholders to gain their perspective on how payment changes affected the buying and selling of physician-administered drugs.
- We reviewed the literature on indicators of quality of care for selected specialties.

Average sales price

Expenditures for Part B drugs increased rapidly, more than 25 percent every year from 1998 to 2003. The payment method was one of the most significant factors driving spending growth. After the Balanced Budget Act of 1997, the Medicare payment rate for covered drugs was set at 95 percent of the average wholesale price (AWP). Despite its name, AWP does not correspond to any transaction price or average transaction price, which often reflects substantial discounts. Rather, it can be thought of as a manufacturer's suggested list price. Individual AWPs are compiled and reported in compendia like the Red Book and First Databank largely on the basis of information supplied by the manufacturers. A series of investigations by the Department of Health and Human Services Office of Inspector General and the Government Accountability Office showed that Medicare payment rates were well above providers' acquisition costs.

Policymakers discussed a number of ways to reform the payment system, including continuing to pay providers a rate based on AWP but requiring a steeper discount, setting payment to a different benchmark tied to transaction prices like ASP, or using competitive bidding to lower prices. In its June 2003 Report to Congress, the Commission examined these policy options. We recognized that every proposed reform of the payment system had drawbacks but that all options, whether administered prices or competition-based, were likely to reduce Medicare payments compared with the payment system then in place. In particular, our analysis suggested that a payment method based on a computed average transaction price, such as ASP, would reduce Medicare payments.

Legislative proposals based on ASP anticipated paying providers a specified percentage above the calculated average price, although they differed as to how high to set the additional payment. The Commission did not recommend that the payment rate be set at any specific percentage

above the benchmark but stated that it should be set high enough to cover the costs of an efficient provider but not so high that it contributes to pharmaceutical price increases. (If payment rates are set well above physicians' purchase prices, manufacturers may raise prices to capture more of the additional payments.) We said that beneficiary access would not be affected as long as the payment rate was set high enough to meet the costs of efficient providers.

After passage of the MMA, Medicare generally reduced the payment rate for drugs and increased payments for drug administration services. In 2005, Medicare began paying for Part B drugs based on 106 percent of ASP, which represents the weighted average of manufacturer sales prices for each product that falls within a Medicare billing code. (A single Medicare billing code can be used for multiple products.) ASP is based on data submitted quarterly by pharmaceutical manufacturers, net of price concessions such as rebates and discounts, and is limited to sales in the United States. The ASP payment rate is based on these transaction prices from two quarters prior. Thus, if manufacturers raise prices in the succeeding quarters, purchasers may have difficulty purchasing products at the Medicare payment rate until the ASP "catches up." On the other hand, if prices go down, either because of competition between therapeutically equivalent branded drugs or because a generic version of a branded drug becomes available, purchasers may buy products at prices significantly below the payment rate until the ASP catches up.

How the average sales price payment system has performed

In the first quarters of 2005, Medicare payment rates for many products decreased dramatically as rates approached acquisition costs. By 2006, payment rates were more stable. When generic products became available or branded drugs competed for market share, the payment rate continued to decline. In other cases, payment rates are increasing. CMS reports that overall the weighted average Medicare payment rate across all drugs rose 0.5 percent for the third quarter of 2006. This rate is based on transaction prices during the first quarter of the year. According to the most recent data, CMS reports that the weighted average Medicare payment across all drugs decreased by less than 1 percent between third and fourth quarter of 2006.[1]

Most physicians have told us that they can still buy most drugs at the Medicare payment level, but all report that margins are slim and there are some drugs they cannot purchase at the payment rate. Physicians, particularly oncologists (who buy the most drugs), report spending considerable time and staff resources seeking the best deals for drugs. Many also noted that they have increased efficiencies in their practices in response to lower drug payments (see discussion on p. 23).

In interviews, physicians, hospital administrators, wholesalers, manufacturers, and consultants identified some structural issues with the way ASP is calculated. We classify these issues into the following categories: data lags, gap between manufacturers' reported ASP and physicians' purchase price, state and local taxes, and bundling.

- ***Data lags.*** The ASP payment rate is set based on transaction prices from two quarters prior. Thus, if manufacturers raise prices in the succeeding quarters, purchasers may have difficulty purchasing products at the Medicare payment rate until the ASP catches up. On

the other hand, if prices go down, either because of competition between therapeutically equivalent branded drugs or because a generic version of a branded drug becomes available, purchasers may buy products at prices significantly below the payment rate until the ASP catches up. Physicians consistently noted that the data lag was their biggest problem with the new payment method. However, few mentioned instances when they benefit from the lag, even though this does occur. Additionally, physicians reported that manufacturers tend to increase prices each quarter for single source drugs without competitors. Price increases are smaller but more frequent than under the previous payment system.

The Congress could require manufacturers to provide data more frequently and CMS could use those data to update payment rates more often. Policymakers would have to consider the possible effects of faster data reporting and payment updates. On the one hand, Medicare would capture price changes more quickly. On the other hand, more frequent updates could have an inflationary effect and lead to more price increases because manufacturers would know that increases would be quickly reflected in the payment rates. Further, CMS would require more time and resources for administration. Keep in mind that the payment rate, which is set above ASP, provides something of a buffer if prices increase.

- ***Gap between manufacturers' reported ASP and average physician purchase price.*** ASP is based on the payments manufacturers receive for their products. When manufacturers sell directly to physicians, the average amount they receive should be the average price physicians pay. However, drugs often pass through a larger distribution chain; wholesalers, specialty pharmacies, and group purchasing organizations may be involved in drug shipping, storing, handling, and price negotiations. Each link in the distribution chain receives payments. If there is a gap between the price manufacturers receive and report and the physician purchase price, ASP may be lower than the average physician purchase price. This can happen in two ways:

  - ASP may include discounts that are not passed on to physicians.
  - ASP may not include wholesale fees that physicians pay.

  For example, manufacturers may offer prompt-pay discounts to wholesalers who pay for their purchases within a specified time frame. Although these discounts are small in percentage terms, they are an important source of revenue for wholesalers and may not be passed on to the final purchaser (such as a physician). Prompt-pay discounts lower ASP because they reduce the revenue manufacturers receive for their products. When these discounts are not passed on to purchasers including physicians, Medicare's ASP may fall below the average price physicians pay.

  Similarly, wholesalers may mark up the price they charge to physicians. These fees may include wholesaler profit, handling, and shipping costs. Manufacturers do not receive more for their product and therefore do not include these fees in calculating ASP. Thus, these markups may result in drug prices that are high relative to the ASP manufacturers report.

  Because the Medicare payment rate is set above ASP, physicians generally are able to purchase products at the Medicare payment rate. However, if a drug is very inexpensive,

wholesaler markups tied to fixed costs may be higher than the actual drug cost. In our interviews, many physicians listed older generic drugs as examples of products they could not purchase at the Medicare payment rate.

The Congress could decide to exclude some of the fees and discounts from ASP calculations. In the Deficit Reduction Act, Congress directed manufacturers to exclude prompt-pay discounts in calculating Medicaid's payment for drugs. Medicare could adopt this approach. The Congress could also mandate a dispensing fee to cover the fixed costs providers face when furnishing drugs to beneficiaries. This fee could be limited to the inexpensive drugs which may be more of a problem. There are several reasons for not making this change. First, the 6 percent above ASP in the formula helps offset the effects of these discounts and charges. Second, in the future, wholesalers might modify their business model if their fees prevent providers from purchasing Part B drugs.

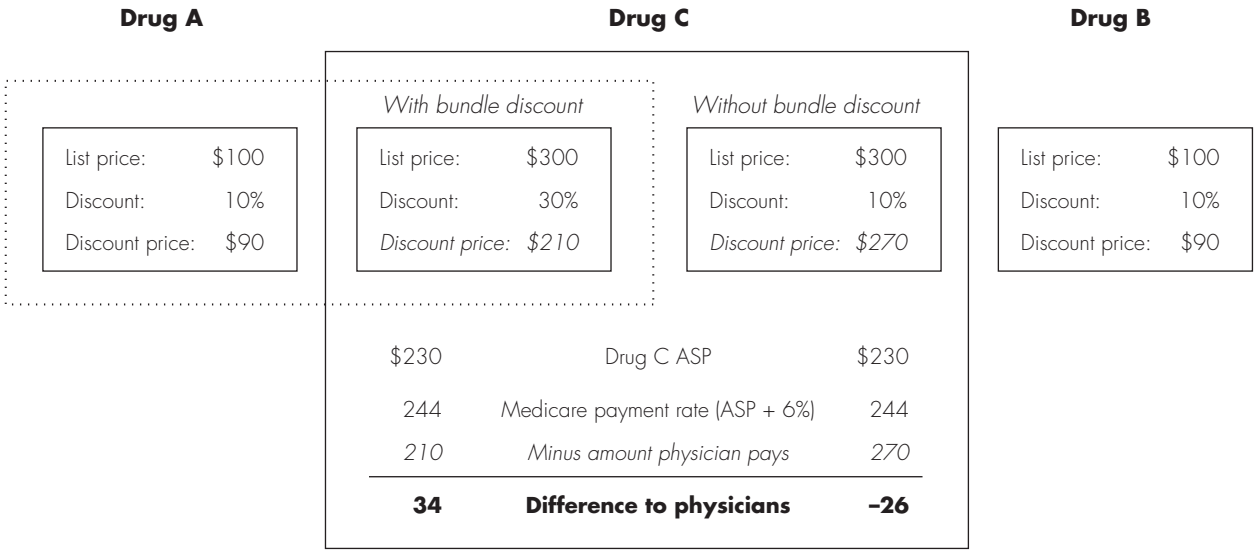
- ***State and local taxes.*** Physicians in some parts of the country report that they pay state or local taxes for Part B drugs, including sales tax and a tax on gross receipts. These taxes effectively reduce drug payment rates for physicians by as much as 2 percent in some areas we visited compared with rates for their peers in other areas. Examples include the state of Washington and the city of Norfolk, Virginia. In some cases, the tax is meant to be charged to patients, but the Medicare program cannot be assessed local taxes and beneficiaries cannot be charged because of a prohibition on balance billing. It is not clear that Medicare could take any action to address this issue, because making allowances in each area that has these taxes would be administratively burdensome and would encourage areas to impose further taxes.

- ***Bundling.*** Some manufacturers offer provider discounts for one of their products contingent on purchases of one or more other products. Many interviewees told us about a specific bundling issue related to the calculation of ASP that posed a problem for them. Currently, there are two drugs, we call Drug A and Drug B, similar products that compete for market share. Although the shift to ASP has resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. In this instance, the manufacturer of Drug A also makes Drug C, a lifesaving drug with no effective competition. It is very unusual to get a large discount on a drug that has no competition, but, in this case, the manufacturer provides a significant discount on Drug C to purchasers who buy Drug A instead of Drug B. These discounts result in a lower ASP for Drug C and a lower Medicare payment rate. The Medicare payment rate for Drug A is higher than it would be if the discount had been allocated to it.

  Physicians see payment differences when Drugs A and C are bundled (Figure 1). Product prices and discounts are hypothetical and used purely for illustrative purposes. In this illustration, the list price for Drugs A and B is $100 and the list price for Drug C is $300. If physicians get the bundled discounts (10 percent for A and 30 percent for C), they have no trouble purchasing either drug at the Medicare payment rate, as pictured in the figure. However, if they prefer Drug B, they lose money each time they buy Drug C, because Medicare's payment rate for Drug C ($244 in the figure) is lower than the price physicians must pay if they do not get the bundled discount.

Figure 1

Physicians can lose money if they do not purchase bundled products



Note: ASP (average sales price). Prices and discounts are for illustrative purposes only.

In the short term, the bundling arrangement results in lower Medicare payment rates for all three drugs. In the longer term, it could drive Drug B out of the market, leading to higher prices for both Drug A and Drug C. Additionally, some physicians indicate that their ability to choose a product based on clinical factors has been compromised. Other manufacturers of single source drugs might also use this method to increase their sales on products with competition. Without guidelines for the allocation of bundled discounts, the bundling methodology undercuts the ASP payment method.

This example represents only one type of bundling arrangement. Bundling arrangements take many forms. For example, some bundling arrangements may include only Part B drugs while others may include both Part B drugs and other products. Similarly, price concessions may be structured in numerous ways. For example, a discount on one or more drugs may be contingent on the purchase of other drugs or on meeting an aggregate expenditure target for a group of products. CMS's policy on reporting discounts may need to change over time to reflect changing market practices but that should not slow down action in this area.

CMS has offered no specific guidance on how bundled discounts should be allocated. The agency could support the accuracy of the ASP methodology by clarifying rules about the way bundled discounts should be allocated under manufacturer reporting requirements.

One option is reflecting the contingencies in the contract. For example, when a discount for one drug or drugs is contingent in whole or in part on the purchase of another drug, CMS could require that manufacturers allocate any additional bundled discounts to reflect the contingencies

in the contract. In other words, allocate the increased discount to the sales of the drug that the discount is meant to increase. This would result in an ASP that more accurately reflects the transaction price of the drugs. For example, in Figure 1, 20 percentage points of the discount for Drug C are contingent on the purchase of Drug A. This discount could be allocated to sales of Drug A in the calculation of ASP.

Another option is to allocate bundled discounts in proportion to the sales of each drug sold under the bundled arrangement. For example, let us assume that Drug A and Drug C in our illustration have a bundled discount equal to $200,000 on total sales of $1 million. If Drug A has sales of $600,000, the manufacturer would allocate 60 percent of the bundled discount to that drug when calculating ASP. This option would parallel bundling requirements under Medicaid and be simpler to administer. However, this method might not capture contingent discounts.

The goal should be to ensure that ASP reflects the average transaction price for drugs. CMS should ensure that guidelines for allocating discounts are clear and that manufacturers can implement them in a timely fashion. The Secretary would not need to audit all contract terms to administer the policy. Rather, the Secretary would randomly audit manufacturer contracts and compare them with the reported ASPs. The Secretary should be prepared to revisit ASP calculation rules to prevent unintended consequences and preserve the integrity of the payment system.

RECOMMENDATION

The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.

Rationale:

The ASP payment method has resulted in substantial savings for the Medicare program and its beneficiaries. To maintain the accuracy of individual ASPs, discounts from bundled drugs should be allocated to ensure that ASP reflects the average transaction price for each drug.

Spending. Indeterminate. This recommendation could increase payments for some drugs and decrease payments for others.

Beneficiary and provider. This recommendation would support access to drugs for beneficiaries and providers by ensuring the integrity of the ASP payment system.

These issues suggest a need to monitor providers' acquisition costs to ensure that they are able to purchase necessary drugs at the payment rate. In the past, the Commission has recommended that the Congress give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare them with average sales price data. The Secretary should also collect data on the acquisition costs of other providers.

Least costly alternative

Our research on the three specialties shows that urologists face an additional payment requirement called the least costly alternative (LCA) policy. The policy applies to payment rates for the drugs they provide to treat advanced prostate cancer and states that the Medicare carrier will not cover the added cost of a more expensive product if a clinically comparable product exists. LCA policies for hormone-suppressing treatments for advanced prostate cancer started in some geographic areas in 1995 and now virtually all areas have these policies.

In 2004, the Office of the Inspector General (2004) recommended that all carriers use LCA policies to determine payment for these drugs. At that time, the policy affected two hormone-suppressing treatments. Currently, six products are in this drug class, ranging in mode of administration from monthly injections to annual implants. All physicians we spoke to agreed there was no difference in clinical efficacy among the products, although patients and physicians might favor one product over another.

Interviewees have complained that the policy is applied inconsistently and changes frequently.

- Some carriers cover all the products under one LCA policy; others may separate injections from implants. Physicians say that combining injections and implants under one LCA policy interferes with their ability to prescribe the best mode of treatment for their patients (AUA 2006). If all products are covered under one LCA policy, the carrier takes the price of the implant, divides by 12 (for 12 months), and estimates an average price. With this payment method, implants are nearly always cheaper than injections. Yet some urologists believe patients should receive hormone-suppressing drugs intermittently to maintain the efficacy of the treatment and improve quality of life. Intermittent treatment is not possible with an annual implant. The physician would have to switch patients to an implant or face losses on any injectable drug.

- Because the ASP for each product changes quarterly, the drug chosen as the LCA may vary from one quarter to another. Additionally, payment rates for each drug must be adjusted for dosage. Consequently, some carriers may determine retrospectively that they have paid incorrectly. Interviewees have complained that carriers sometimes go back years to recalculate LCA and ask for return of overpayments.

- In some regions, specific products are "grandfathered" and exempt from LCA requirements. If physicians begin treating patients with one drug, they may continue prescribing the drug and get paid 106 percent of ASP for each dose. But if they begin patients on another drug, they have to switch patients to the LCA or lose money each time they administer the drug if it is no longer least costly. Without any clinical evidence to support the need for grandfathering one product over another, our concern is that reimbursement may determine clinical decisions.

The Commission supports LCA policies. However, they need to be applied in a clinically appropriate and consistent manner. The drugs used to treat advanced prostate cancer are among a small number of pharmaceutical products for which CMS or any of its contractors apply an

LCA policy. Other classes of drugs may contain clinically equivalent products for which an LCA policy might be applicable. Such a policy, if applied consistently, could stimulate price competition among different branded products but allow beneficiaries to pay an additional sum if they and their physicians choose the more costly drug.

The way carriers are implementing the LCA policy for drugs to treat advanced prostate cancer is troubling. The Commission recognizes that in some instances local coverage determinations promote innovation and flexibility. However, the Commission is concerned that local policies are not always administered appropriately. It would thus be useful for CMS to clarify the carriers' LCA policies—a national coverage determination might be appropriate in this case.

Competitive acquisition program (CAP)

The MMA mandated the establishment of a competitive acquisition program (CAP) in 2006 as an alternative way for physicians to acquire physician-administered drugs. The goal of the program was to increase competition for Part B drugs: CAP vendors, who would purchase large quantities of drugs, could negotiate lower prices with pharmaceutical manufacturers and produce Medicare savings. The program also was designed to eliminate financial incentives for physicians to prefer one drug over another. Additionally, small practices that are unable to purchase drugs at the Medicare payment rate would have another way to acquire drugs and could continue to administer drugs in their offices.

Under CAP, organizations like wholesalers and specialty pharmacies submit bids to Medicare to become designated vendors for Part B drugs. Each year, physicians choose whether to purchase and bill for Part B drugs or receive them through a Medicare-designated vendor. Vendors purchase and dispense drugs to physician offices on a prescription-by-prescription basis. Medicare pays the vendors directly and the vendors bill patients for required copayments.

CAP was implemented on July 1, 2006, with Bioscrip as the sole designated vendor. In the initial enrollment period, 307 physician practices enrolled in and began using CAP. Physicians in specialties with the highest Medicare Part B drug spending were least likely to enroll in the program (Friedman 2006).

The physicians we interviewed were not willing to participate in CAP as it was implemented. Key criticisms of the program included the following:

- Vendors can stop supplying drugs for beneficiaries who do not pay their copayments in a timely fashion. If this happens, a beneficiary's care can end in the middle of treatment.
- Offices have to maintain separate inventories for each patient covered through the CAP program. If patients cannot receive treatment on a given day, as is frequently the case because of their medical condition, the office has to return the drug to the vendor instead of using it at the next appointment.

- The CAP program requires physicians to appeal all claim denials even if they do not believe the time and effort required to mount the appeal is an effective use of practice resources.
- Physicians with satellite offices in rural areas cannot participate in the program because they often cannot accept drug deliveries and mix drugs in their satellite offices.
- Urologists point out that some of the drugs most important to them are not among those the CAP vendor supplies.

In our January 2006 Report to the Congress (MedPAC 2006), the Commission discussed how to make the CAP program more workable for physicians. We recommended that the Secretary allow an exception to the CAP delivery rules for rural satellite offices of providers. We also discussed allowing a drug replacement model under the CAP program. Under this model, physicians would estimate the type and quantity of drugs they required for all their Medicare patients for a week. The vendor would supply the drugs. When a drug was used, the physician would notify the vendor, who then would bill Medicare and the beneficiary for the drug and send a replacement for the administered drug to the practice. This model would lessen the administrative burden on physicians and vendors.

The Congress might also consider permitting physicians to acquire some drugs through the CAP program without requiring them to order all their covered drugs through the vendor. This approach could create a safety net for physicians who are unable to purchase certain drugs at the Medicare payment rate. More study is needed to consider the implications of this approach.

Medicare spending for drugs and drug administration

The change to an ASP-based payment system for Part B drugs affected expenditures for urologists, rheumatologists, infectious disease specialists, and medical oncologists. These specialties differ in terms of the volume of physician-administered drugs they provide and the proportion of Medicare billing they derive from drugs. Yet, in all cases, we saw a similar pattern. From 2004 to 2005, when the payment rate changed from 85 percent of AWP to 106 percent of ASP, total charges for the specialty (including drugs, drug administration, evaluation and management, tests, and other procedures) increased but spending on drugs decreased. The decline in expenditures for drugs ranged from 1 percent for rheumatology to 52 percent for urology. Part of the reduction in spending is attributable to lower prices. That is, ASP resulted in substantial price savings for Medicare on nearly all drugs, and those changes in payment rate drove decreased spending.

We analyzed carrier claims submitted by urologists, rheumatologists, infectious disease specialists, and medical oncologists and calculated changes in allowed charges, volume of services, and payment per service for drugs and other services for each specialty. To calculate volume, we held payment rates constant and looked at the dollar change in the volume and intensity of services. We calculated changes in payment rate as the difference between charges at constant prices and the actual charges.

Table 1

Part B drugs as a percentage of Medicare allowed charges and volume of services

	Allowed charges				Volume of services			
Specialty	**2002**	**2003**	**2004**	**2005**	**2002**	**2003**	**2004**	**2005**
Urology	43%	42%	36%	20%	38%	37%	36%	31%
Rheumatology	42	50	49	46	39	47	51	50
Infectious disease	7	7	8	6	6	7	10	8
Medical oncology	76	78	72	70	71	73	75	74

Note: Medical oncology specialties include hematology, hematology/oncology, and medical oncology.

Source: C. Hogan, Direct Research, analysis of Medicare physician-supplier procedure summary file, 2002–2005.

The volume of drugs provided by specialty varied considerably from 2004 to 2005. The overall volume of claims for Part B drugs increased in 2005, but urologists and infectious disease specialists provided fewer physician-administered drugs in their offices than they had in 2004: 21 percent decrease for infectious disease specialists and 16 percent decrease for urologists. Because the volume of drugs infectious disease specialists provide in their offices is so small, percentage changes can be misleading. Volume increased by 24 percent for oncologists and 9 percent for rheumatologists. In our report on chemotherapy services, we found that the increase in the volume of drugs oncologists provided was largely driven by the substitution of newer, more expensive therapies for older products (MedPAC 2006).[2]

Changes in average payment per drug from 2004 to 2005 ranged from a decrease of 9 percent for drugs provided by rheumatologists to a decrease of 43 percent for urology drugs. For example, the Medicare payment rate for the drug billed most by urologists, leuprolide acetate, fell almost 50 percent. Payment rates for all hormone-suppressing advanced prostate cancer drugs also were affected by LCA policies applied by local carriers (discussed on p. 10).

Each specialty's drug payments largely depend on a few types of drugs and some specialties are the major providers of certain drugs. For example, urologists provide about 90 percent of all Part B units for leuprolide acetate suspension and goserelin acetate implant, the most commonly used hormone therapies for advanced prostate cancer. Rheumatologists are the main suppliers of infliximab, a biologic for treating rheumatoid arthritis and Crohn's disease. However, infectious disease specialists are not the primary providers of any drugs although they did provide 28 percent of vancomycin and 34 percent of daptomycin, two antibiotics. In contrast to the drugs supplied by the other specialties, more units of these products were provided in hospital outpatient departments than in physician offices.

The payment changes affected drugs as both a percentage of charges and volume of services provided to Medicare beneficiaries (Table 1). In general, charges were more affected than volume as Medicare began paying for drugs at prices closer to what physicians were paying. For all

specialties, drugs as a percentage of total billing fell between 2004 and 2005 but the fall was steepest in the case of urology.

- For urologists, drugs fell from a high of 43 percent of all their Medicare billing in 2002 to 20 percent in 2005. The volume of drugs provided as a percentage of total services also decreased but less dramatically, from 38 percent to 31 percent.
- Infectious disease specialists experienced a decline in drugs as a percent of total charges from 2004 to 2005 (8 percent to 6 percent). The volume of drugs as a percentage of their Medicare services fell from 10 percent to 8 percent.
- For rheumatologists, drugs as a share of total Medicare billing decreased slightly from 49 percent to 46 percent but volume was relatively constant from 51 percent to 50 percent of total services. Both numbers represent increases from 2002, however, when drugs accounted for 42 percent of charges and 39 percent of volume of services.
- For oncologists, drugs as a percent of total charges also fell from 2004 to 2005 (72 percent to 70 percent), and the volume of drugs as a percent of services fell slightly from 75 percent to 74 percent but was still higher than it was in 2002 (71 percent).

Experiences of individual specialties

Each of the specialties made at least some changes to their practices in response to the payment changes.[3] Urologists made the most significant changes to their clinical practices, providing drug treatments to fewer Medicare beneficiaries. Rheumatologists increased the volume of drugs they provided to beneficiaries but Medicare expenditures for drugs fell slightly. Unlike rheumatology and urology, infectious disease specialists furnish most of their drugs in hospital outpatient department and facility settings. Only the larger practices offer physician-administered drugs in their offices.

Urologists reduced volume of drugs provided to beneficiaries

Of the three specialties examined for this report, urologists made the most significant changes to their clinical practice. Before the payment changes, they accounted for 17 percent of Part B drug spending, with only oncologists and pharmacy suppliers at a higher level of spending (MedPAC 2003). Since Medicare's drug payment changes were implemented, the volume of drugs urologists provided to beneficiaries has declined considerably.

Urologists provided 16 percent fewer drugs to Medicare beneficiaries in 2005 than in 2004 (Table 2). From 2003 to 2004 (data not shown), volume increased by 1 percent. The number of drug administration services, evaluation and management visits, and other Medicare services all increased annually during this period.

We examined whether the observed decline in drug volume was caused by a decrease in the number of beneficiaries receiving drugs, lower doses of the drugs, or less frequent

Table 2

Trends in volume of services provided by urologists

	Volume of services (in billions)			Percent change	
	2003	2004	2005	2003–2005	2004–2005
Total	$2.71	$2.84	$2.83	4%	0%
Drugs	1.02	1.02	0.86	–14	–16
Drug administration	0.05	0.05	0.05	5	3
Evaluation and management	0.58	0.61	0.64	10	5
All other services	1.07	1.16	1.28	20	10

Note: Volume is measured as total charges with payment changes held constant. Drug administration payments were subject to transitional adjusters in 2004 (32 percent) and 2005 (3 percent).

Source: C. Hogan, Direct Research, analysis of Medicare physician-supplier procedure summary file, 2002–2005.

drug administration. Our analysis shows that the volume decrease was attributable to fewer beneficiaries receiving hormone treatment for prostate cancer.

Declines appear to have been the greatest in the practices and geographic areas that had been providing the most drugs. For example, from 2004 to 2005, the number of urologists in our sample providing $400,000 or more in drug spending at constant prices declined by nearly one-fifth.[4] We find that states with the highest annual per capita spending on these drugs generally showed the greatest volume reductions in 2005. For example, beneficiaries seeing urologists in New Jersey and Florida (which provided among the highest per capita volume of these drugs in 2004) had volume reductions of 23 percent and 18 percent, respectively.

Examination of spending trends for the two drugs urologists administered most frequently (leuprolide and goserelin, both used to treat prostate cancer patients) confirmed this volume had not been shifted to other specialties or settings. Office-based urologists continue to provide more than 85 percent of each of these products.

We cannot be definitive in explaining these declines in drug use, but discussions with experts and our review of the literature suggest several possible explanations. With expanded screenings for prostate cancer, more low-risk cancers are detected. Rather than pursue a watchful waiting approach, many patients with localized prostate cancer elected to undergo hormone treatment, either alone or in combination with another therapy (Cooperberg et al. 2003, Meng et al. 2002). In fact, rates of hormone therapy increased from almost 12 percent of patients with prostate cancer (all ages and risk categories) in 1991 to 41 percent in 1999 (Shahinian et al. 2005a). Even the use among patients with localized prostate cancer increased four-fold, despite the lack of demonstrated benefit for low-risk patients.

In recent years, researchers have found evidence that the hormone-suppressing drugs increase the risks of heart disease, diabetes, and hip fractures (Keating et al. 2006, Shahinian 2005b). These findings may have discouraged some use, particularly when the benefits for low-risk patients remain unproven. Physicians may have also increasingly recommended that patients take a break from hormone therapy as a way to maintain the drugs' effectiveness and improve their quality of life. In addition, according to one expert, physicians may have been discouraged by the smaller profit from prescribing therapies for patients in cases where the benefits remain unproven. Although more research is necessary to draw a conclusion, we saw no indication that quality of care was affected by changes in practice patterns, but, as discussed later, our ability to measure quality changes is limited.

Interviews with urologists provided little insight into the reduction in volume of services. Although they spoke of making many of the general office management changes we discuss on p. 22, most urologists interviewed seemed more concerned about general Medicare physician fee levels than about drug payments. A small number noted that further reductions in drug payments might encourage them to treat more patients surgically, assuming that medical evidence continues to support this treatment option as an appropriate alternative. One patient advocacy group told us that physicians were increasingly recommending surgical approaches to block the hormones that fuel the cancer growth. To date, however, widespread substitution of surgery for hormone therapy has not occurred. In 2005, more than 140,000 beneficiaries were treated with drugs but only 8,200 orchiectomies were performed. In general, the number of orchiectomies has been declining steadily although there was a small increase in 2005. Before the advent of hormone therapy, surgical approaches were the predominant form of blocking hormones.

Rheumatologists made small changes in their practice patterns

Rheumatologists use a small array of drugs in their practices and rheumatology practices seem to be making few changes. Rheumatologists provided more drugs to beneficiaries in 2005 than in 2004, although Medicare expenditures for drugs fell slightly. Total Medicare spending for all rheumatology services increased by 5 percent, the largest increase for any of the specialties studied in this report.

Rheumatologists increased the total volume of services they provided by 11 percent and the volume of drugs by 9 percent in 2005 (Table 3). The greatest increase was in drug administration services because coding changes allowed specialists to bill for more infusion services.

Infliximab, the agent provided most for treatment of rheumatoid arthritis, entered the market in 1999. As a result, rheumatologists have rapidly increased their use of drugs this decade. For example, the volume of drugs they provided increased by 49 percent from 2002 to 2003. In 2005, the volume increased but at a much slower rate.

Medicare's spending on infliximab was constant despite a 10 percent increase in the units provided. Some rheumatologists reported having trouble finding the drug at a price at or below Medicare's payment. One practice also noted that the drug is costly to administer, because it takes a staff member approximately 30 minutes to prepare it for infusion. Some rheumatology practices

Table 3

Trends in volume of services provided by rheumatologists

	Volume of services (in billions)			Percent change	
	2003	2004	2005	2003–2005	2004–2005
Total	$0.80	$0.90	$1.00	25%	11%
Drugs	0.38	0.46	0.50	33	9
Drug administration	0.02	0.02	0.05	161	129
Evaluation and management	0.27	0.28	0.28	5	3
All other services	0.14	0.15	0.17	22	12

Note: Volume is measured as total charges with payment changes held constant. Drug administration payments were subject to transitional adjusters in 2004 (32 percent) and 2005 (3 percent).

Source: C. Hogan, Direct Research, analysis of Medicare physician-supplier procedure summary file, 2002–2005.

send patients using infliximab to hospitals to receive their infusions, but most others continue to provide drugs in the office.

Rheumatologists report little change in clinical practice. According to one interviewee, a poll of rheumatologists in Virginia, conducted one year after the ASP-based payment system was implemented, reported that only 1 of about 60 practices across the state had stopped doing infusions because of the new payment system; 3 practices said they were considering dropping infusions.

Some self-administered drugs covered under Part D compete with infliximab. The self-administered drugs are fairly expensive under Part D, often subject to 25 percent coinsurance as "specialty" drugs. Rheumatologists generally confirmed that they consider these drugs interchangeable for the conditions they treat, although individual patients may fare better on one or the other. Before Part D was implemented, rheumatology respondents reported that nearly all Medicare patients without drug coverage received infliximab because of Part B coverage for the drug. Now, physicians may work with patients to determine whether it makes more sense to use a drug that would be covered under Part D or Part B, depending on where their spending is in relation to the coverage gap and catastrophic coverage.

Patients who use Part D may quickly reach their coverage gap, but no such limit applies to their care under Part B. A few physicians reported seeing patients who had fallen into the coverage gap neglecting treatment or trying to stretch out their drug regimens until their coverage started again. One doctor related the story of a patient with rheumatoid arthritis who had cut back on his treatments with a Part D drug. By taking fewer shots, he was well enough to stay out of the hospital but was in considerably more pain than when he took the full regimen of drugs. Another physician reported starting a patient on a Part B drug when she reached the coverage gap for her

Table 4

Trends in volume of services provided by infectious disease specialists

	Volume of services (in billions)			Percent change	
	2003	2004	2005	2003–2005	2004–2005
Total	$0.42	$0.48	$0.50	17%	4%
Drugs	0.03	0.05	0.04	37	–21
Drug administration	0.01	0.02	0.02	59	26
Evaluation and management	0.37	0.40	0.42	14	6
All other services	0.01	0.01	0.01	22	9

Note: Volume is measured as total charges with payment changes held constant. Drug administration payments were subject to transitional adjusters in 2004 (32 percent) and 2005 (3 percent).

Source: C. Hogan, Direct Research, analysis of Medicare physician-supplier procedure summary file, 2002–2005.

Part D drug treatment. Coverage with Part D has some advantages, however. Some respondents noted that, unlike Part B, once a patient reaches the catastrophic limit, Part D coverage is more comprehensive, with the patient responsible for 5 percent coinsurance on drugs for the rest of the calendar year compared to 20 percent under Part B.

Infectious disease specialists provide a small volume of drugs in their offices

Part B drugs make up a small part of this specialty's Medicare revenues, a much lower share than for the other specialties. Unlike rheumatology and urology, infectious disease specialists furnish most drugs in hospital outpatient and other facility settings, where they typically practice. Only the larger practices offer physician-administered drugs in their offices.

Infectious disease specialists provided 4 percent more services of all kinds to Medicare beneficiaries in 2005 than in 2004 (Table 4). However, Medicare Part B drug spending and volume of services declined more than 20 percent in 2005, after an increase of 37 percent from 2003 to 2004. We should regard these changes with caution because the absolute number of total charges was small and varied little, falling from about $40 million to $30 million. However, the 2005 decline may indicate that once the provision of Part B drugs became financially unattractive, the minority of practices that had furnished the drugs in their office shifted some of these services back to the hospital and post-acute care settings where these services are typically provided. This shift may be problematic because it could expose certain beneficiaries (e.g., those with compromised immune systems) to a higher risk of infection present in hospitals and post-acute care facilities.

Effect of payment changes on physicians' practices

The Congress required the Commission to examine the effects of the changes in Medicare payments on physician practices. Last year, we reported on how the payment changes had affected oncology practices. This year, in examining urologists, rheumatologists, infectious disease specialists, and oncologists, we found both similarities and differences in the ways specialties adapted to the payment changes. In each specialty, physicians continued to treat Medicare beneficiaries with physician-administered drugs. Interviewees at most practices reported sending some Medicare patients, generally those without supplemental insurance, to a hospital for treatment, and they reported having to increase practice efficiencies to make ends meet.[5] Differences among specialties depended largely on how significant physician-administered drugs were as a percentage of their revenues.

We also detected some new trends in interviews this year. ASP seems less volatile than it was in 2005. Many private payers and Medicaid have also changed the rates they pay, often using an ASP-based system, although this varied by location. We detected a difference between larger and smaller practices in the ability to handle the payment changes.

Changes in where beneficiaries receive care

All practices we interviewed continue to treat most of their Medicare patients in their office, but Medicare patients without supplemental insurance are often sent to the hospital for infusions. Physicians who sent patients to the hospital for treatment in 2004 and 2005 continued to do so in 2006. Most respondents said that the proportion of patients they sent to the hospital remained steady, but some practices reported sending more than in previous years. For example, one practice manager reported in 2005 that only patients receiving intravenous immunoglobulin (IVIG) were sent to the hospital for treatment, but in 2006 that practice was referring all Medicare patients without supplemental insurance to the hospital. Some practices had begun sending patients to the hospital to receive treatments only in 2006.

We cannot quantify the number of patients affected by shifts in site of care. Claims data for 2005 do not indicate a faster increase in the volume of physician-administered drugs provided in hospital outpatient departments relative to physicians' offices. Generally, the volume of drugs provided in hospital outpatient departments increased in 2005 but not more quickly than the volume of drugs provide in physician offices. The volume of drugs provided in hospital outpatient departments (HOPDs) is far smaller than that in physician offices. In 2005, Medicare spent about $2 billion on separately billed drugs in the hospital compared with $10 billion in physician offices.

Because of the high cost of treatments, beneficiaries without supplemental insurance may not have the funds to pay their 20 percent copayments at the doctor's office. Many practices face a significant loss if patients do not pay their copayments. Case workers at the National Patient Advocate Foundation and a respondent at one hospital reported seeing an increasing phenomenon of physicians requiring patients to pay their copayments before treatment. Some practices ask patients to show that they have the funds available for an entire course of treatment

before it begins. In these practices, patients who cannot prepay for their treatment may be sent to the hospital for their care. Many hospitals still accept patients regardless of ability to pay and are able to write off some beneficiary copayments as bad debt.

Depending on the level of Medicaid reimbursements, Medicare beneficiaries who are also eligible for Medicaid (dual eligibles) may be sent to the hospital for treatment. In some states, Medicaid's reimbursement does not fully cover the beneficiary's 20 percent share.

Most practices interviewed reported having a blanket policy for sending all dual eligibles and patients without supplemental insurance to the hospital for treatment. Other practices send only those patients without supplemental insurance who are receiving specific, expensive drugs or drug regimens. One respondent expressed concern that practices that choose whether to administer drugs on a drug-by-drug basis may be damaging the coordination of care for their patients who must receive drugs in multiple settings.

The hospitals in our sample gave mixed reports about the extent of this shifting of patients. One hospital reported only a marginal increase in infusion patients, whereas another reported a 20 percent to 25 percent increase. The hospital that saw a large increase reported it was a financial burden; patients were referred there because they could not pay their doctors' copayments, so they are unlikely to pay the hospital for their care.

To examine the impact of this shifting on Medicare and beneficiary spending, we compared the payment rates associated with drug regimens administered in physician offices versus hospital outpatient departments for 2006. We did not find a pattern of higher payments in either setting. Since the MMA, payment methods and rates for the drugs and drug administration services have changed yearly. The cost differences shown in this section are illustrative and likely to change in 2007.

To compare costs, we asked specialty societies for drug, drug administration, and dosing details used in typical treatment regimens for prostate cancer, rheumatoid arthritis, breast and lung cancer, and bacterial infection. Because of the variety of drugs available to treat these conditions, the regimens we priced provide only a snapshot of the payment differences.

For these prostate and bacterial infection regimens, total Medicare payments and the patient's copayments are higher in the hospital (Table 5). The two regimens to treat rheumatoid arthritis and cancer have higher total Medicare payments and patient copayments in the physician office. In the hospital, Medicare also pays 70 percent of the aggregate unpaid patient bad debt.

These estimates include payment rates for a single dose, which should be multiplied over the course of the treatment. In cases such as advanced prostate cancer and rheumatoid arthritis, the differences in payments can be multiplied over an indefinite period of time. Additionally, the estimates do not consider the extra lab tests and physician visits that sometimes result when patients are treated in both physician offices and the hospital. Infectious disease doctors might send patients to a skilled nursing facility or an inpatient hospital department for their infusions, as these sites were often used for the specialty's infusions before the payment changes. Medicare costs in these cases are higher.

Table 5

Payments for drug treatments are sometimes higher in physician offices, sometimes in outpatient departments, 2006

	Physician office	Hospital outpatient department
Advanced prostate cancer regimen: Leuprolide acetate suspension		
Drug payment	$232	$224
Drug administration payment	46	68
Total payment	278	293
Patient's copayment	56	59
Rheumatoid arthritis regimen: Infliximab		
Drug payment	1,637	1,604
Drug administration payment	91	121
Total payment	1,728	1,725
Patient's copayment	346	345
Bacterial infection: Vancomycin		
Drug payment	6	N/A*
Drug administration payment	77	121
Total payment	84	121
Patient's copayment	17	24
Breast and lung cancer regimen: Carboplatin/Paclitaxel		
Drug payment	140	120
Drug administration payment	352	358
Total payment	492	478
Patient's copayment	98	85

Note: N/A (not applicable). Payments do not include evaluation and management fees. In the physician office, patient copayment equals 20 percent of the total payments. In the hospital outpatient department, it equals the sum of the patient copayments associated with the regimen as listed in addendum A of the hospital outpatient department fee schedule.
*Payment for vancomycin is included in the hospital outpatient department drug administration payment.

Source: MedPAC analysis of physician and hospital outpatient department final fee schedules for 2006.

Differences in care between physician offices and hospital outpatient settings

Interviewees did not agree on whether the care furnished in physician offices was comparable to that furnished in hospital outpatient settings. Similar to our findings last year with oncologists, physicians generally thought the setting where they practiced had higher quality of care.

Physicians gave several reasons for preferring office-based care. Some practices told us there was less continuity of care in hospital outpatient infusion centers because patients saw different clinicians each time. Some clinicians noted that this lack of continuity could result in nurses being slower to detect the beginning signs of adverse drug reactions in patients they did not know. Some office-based clinicians also thought that the staff at hospital infusion centers were less specialized and might not recognize the signs of adverse drug reactions or dosing problems.

Another concern was the greater risk of infection in hospital settings, particularly for immune-compromised patients. Hospital outpatient infusion centers do not always have a separate area to infuse immune-suppressed patients. In these instances, patients are infused next to other patients or are admitted as inpatients to ensure a sterile environment for the infusion.

Physicians mentioned several quality-of-life concerns that contributed to their preference for office-based care. Many hospital-based treatments require patients to be assessed first by their physician, thus requiring two visits per treatment. In addition, hospital treatments generally take longer because patients need to register at each visit and waiting times are longer. Some hospitals use their infusion space at different times for oncology and non-oncology patients, which may give patients less flexibility in when they can be treated.

Clinicians who practiced in hospital outpatient settings had very different views about the quality of care in their settings, arguing that they are more heavily regulated, resulting in more quality guarantees for patients. In addition, staff and resources are on hand to treat severe adverse reactions, such as cardiac arrest with infliximab. These resources may not be available in a physician office.

Changes in practice operations

Most practices reported they had made at least some changes to lower their expenses, particularly drug and staffing costs. Less frequently, we heard about changes that had influenced, or were likely to influence, treatment decisions. Because chemotherapy makes up a large share of their revenues, oncologists consistently described large changes in their practice operations. They directed many strategies at becoming more efficient—such as finding the best drug prices and managing their drug inventory. Other strategies targeted generating more revenue—charging for all services furnished, breaking up services into separate visits, and hiring financial advisors to help patients manage their cost sharing. Other specialists reported fewer changes to their practice operations.

Respondents report needing to carefully manage their business practices

A number of practices described how the new payment system has required them to become more efficient: more closely watching inventory, staffing, drug prices, site of service, and prompt-pay discounts. One respondent said that management has become critical, suggesting that practices need to become good business managers to survive. If they manage carefully, he argued, practices can live within the reduced reimbursements from Medicare.

- ***Monitoring prices.*** Practice managers report that they constantly monitor which drugs physicians can afford to give in the office. Each quarter when the new Medicare payment rates are released, practice managers compare the numbers with the prices they pay and report to physicians which drugs and drug regimens the practice obtains at a loss or with a margin. In some cases, physicians switch their standard treatment from one drug to a clinical equivalent, based on reimbursement (although many drug treatments do not have appropriate alternatives). Drugs that treat the side effects of chemotherapy are more likely to be switched than the chemotherapy drugs. Some practices maintain that the pricing is important for them to understand but does not affect their clinical decisions. In a few cases, practices send patients to the hospital for treatment if they need a drug whose reimbursement level is below the practice's acquisition cost. Some urology practices now require patients to purchase certain drugs at a pharmacy and bring them to the physician office for administration.

- ***Reduced inventory.*** In 2005 and 2006, practices reported keeping smaller drug inventories, ordering only what they predict they will need within the next few days or, at most, the next week. This procedure allowed them to respond quickly to price changes and avoid tying up large sums of capital. Buying in smaller quantities may prevent practices from receiving volume discounts, but at least one pricing expert we spoke with indicated that volume discounts have become less common generally. One practice told us it no longer prepared drugs before a patient showed up for an appointment, as a way to limit waste due to no-shows.

- ***Prompt-pay discounts.*** Several respondents said that their practices take advantage of prompt-pay discounts offered by wholesalers whenever possible. This type of discounting is becoming a more common part of the pricing model, although, as discussed below, practices are frustrated that the use of these discounts lowers the ASP. (Prompt-pay discounts are discussed further on p. 6)

Practices changed personnel policies

In an effort to control costs, some practices changed the mix of personnel in their offices or compensation policies. Strategies varied. In some cases, offices hired additional personnel to increase efficiencies. For example, some larger practices hired pharmacists to check drug prices, purchase drugs, and mix drugs. Practices hired social workers to help beneficiaries find sources of financial assistance for their treatments. Other practices hired personnel to perform more administrative functions and allow nurses more time with patients.

Other practices reported they had lowered personnel costs by reducing the size of their staff,

offering fewer benefits, freezing salaries, or delaying raises. In past years, oncologists had discussed the need to offer competitive salaries and benefits to hire experienced staff, especially nurses. They acknowledged that reducing benefits and freezing salaries made it harder to attract and retain staff. Although no interviewees reported laying off staff, two said they had reduced their staff through attrition. Two oncology practices in different regions that have multiple infusion centers reported they had closed or were planning to close at least one satellite office. These practices found the reductions in payments from Medicare and some other payers were making it difficult to maintain the nursing staff required to handle the patient volume at satellite offices.

Larger practices found it easier to adapt to the payment changes

Larger practices were more likely to say they already had the systems in place to manage changes in reimbursement, such as reduced inventory and taking advantage of discounts. Smaller practices were more likely to say they had made changes in management in reaction to the payment changes.

Larger practices are better able to employ specialized staff. For example, individuals who specialize in drug purchasing or in reimbursement can devote more time to analyzing drug prices and payment rates. Several practices also said they had hired, or were about to hire, a social worker to help them maximize revenue by making sure patients were enrolled in Medicaid and other programs that cover the costs of their care.

The size of the practice can also directly affect the price paid for drugs. When they purchase larger volumes of drugs, large practices can negotiate discounts and rebates from manufacturers and suppliers. Large practices also tend to have enough cash flow to pay for the drugs they order before they are paid by Medicare, allowing them to take advantage of prompt-pay discounts.

Practice managers mentioned needing a large number of infusion chairs to make the service viable and keep their per infusion costs low. For example, staff can monitor several patients at one time, reducing the cost of care for each patient. One practice discussed scheduling patients by the amount of time their infusions took to ensure few empty chairs when the office was open.

Several practices noted that it is more difficult for small practices to achieve the economies of scale necessary to continue providing drugs in the physician's office. Although we were not able to interview any practices that made such a decision, we heard reports of practices that decided to no longer provide drugs in the office. One practice consultant we interviewed reported that several solo practice physicians had been on the verge of bankruptcy; with the consultant's help, they had improved their situations through a combination of improving their coding practices and stepping up their ability to obtain drugs at lower prices. They accomplished the latter with the help of a pharmacy specialist who works with several practices to negotiate better prices—in effect getting some of the efficiencies of scale of a larger practice.

Effects of payment changes on quality of care

The MMA mandate asked the Commission to examine the effects of payment changes on quality of care. For each specialty, we looked at the most common condition that requires physician-administered drugs and found that there is not a uniform set of quality or outcomes measures across them. This is not surprising given the range of conditions, treatments, and risks associated with the diseases and treatments. For example, the measures appropriate for a chronic condition such as rheumatoid arthritis differ from those that are relevant to an acute episode, such as a bone infection. Practices may collect some quality and outcomes data, either informally or using standard instruments, but Medicare does not. Because Medicare claims data do not include this information, we could not analyze whether the payment changes affected the quality of care that beneficiaries received.

Further complicating the evaluation of the quality of care is the lack of convincing evidence about the most effective treatment for some conditions. For these conditions, the uncertainty about the best course of treatment results in wide variation in practice patterns. For example, the evidence supporting the most effective treatment for clinically localized prostate cancer is mixed (Albertsen et al. 2005, Bill-Axelson et al. 2005, Pisansky 2006). As a result, treatment options include radiotherapy, surgery, and watchful waiting (American Urological Association, National Comprehensive Cancer Network). Studies directly comparing the risks and outcomes associated with treatment alternatives will help physicians and their patients select the most appropriate treatment (Potosky et al. 2000, 2001; Cooperberg et al. 2005; and Klotz 2005). Patients' attitudes toward the risks associated with each treatment option may play a larger role in selecting a treatment when clear superiority of one alternative over another is undocumented.

For the specialties with high Part B drug spending, we identified the most common conditions treated in the Medicare population that require physician-administered drugs:

- prostate and bladder cancer (urology),
- rheumatoid arthritis (rheumatology), and
- antibiotic-resistant infections.

For each condition, we discuss quality measures relevant to the treatment options that involve physician-administered drugs. We also discuss what information is available in Medicare administrative (i.e., claims) data and whether other national outcome data sets include these measures.

Prostate and bladder cancers

Quality and outcome measures for these conditions include rates of adverse drug reactions, mortality and disease progression, and complications. Patients' ratings of their overall health and urinary symptoms are used to evaluate satisfaction with and effectiveness of the treatment.

Bladder cancer

Patients with bladder cancer may be treated with chemotherapy or immunotherapy agents placed directly in the bladder. Guidelines developed by the American Urological Association (AUA) discuss several appropriate outcome measures including death attributable to the disease, adverse drug reactions, probability of tumor recurrence, risk of tumor progression, and complications from the treatment (AUA 1999). Condition-specific complications that could be tracked include local bladder symptoms (such as painful or frequent urination) and systemic symptoms (e.g., infection or flu-like symptoms). Process measures that evaluate catheter care and drug administration might help practices improve these aspects of treatment.

Medicare does not directly collect any of the process or outcome measures. Medicare claims also do not contain information about the extent and aggressiveness of the patient's disease that physicians use to assess risk and to guide decisions about the most appropriate treatments. These data would also be useful for risk adjustment, so that valid comparisons can be made across patients and the physicians who treat them.

Prostate cancer

Patients with prostate cancer may be treated with hormonal therapy involving physician-administered injections, although other treatment options exist. Outcome measures for these patients include survival rates at 5, 10, and 15 years; disease progression rates; and complications from treatment (e.g., increased fatigue and sexual dysfunction).

Medicare does not directly collect these quality and outcome measures. It may be possible to calculate some of the measures (such as survival rates and certain complication rates) from examining the claims' history for a patient. One database, the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE™), contains many clinical and health-related quality-of-life outcome measures and demographic information for a nonrandomized set of patients from selected sites around the country.

Rheumatoid arthritis

In chronic diseases such as rheumatoid arthritis, physicians can slow disease progression but remission (or death attributable to the condition) is unlikely. Therefore, mortality and survival rates are less meaningful than measures of disability and pain. Physicians who administer drugs to patients with rheumatoid arthritis typically gather information about the functional status and joint inflammation or erosion, sometimes using standardized instruments. The most commonly used instruments to measure disability are the Health Assessment Questionnaire and the Arthritics Impact Measurement scale (Kvien 2002).

The American College of Rheumatology (ACR) developed a starter set of quality measures for rheumatoid arthritis that includes the following:

- the elements of a patient's history and physical exam (such as a joint exam, a functional status assessment, and a measurement of pain),

- treatment with disease-modifying antirheumatic drugs for active cases unless contraindicated or documented patient refusal, and
- periodic modifications to the treatment plan when there is evidence of increased disease activity (ACR 2006).

The ACR's practice guidelines include recommended frequencies of lab monitoring, which could form the basis of a process measure (ACR 2002).

Medicare does not gather disability or pain measures. It might be possible to use claims data to confirm certain drug treatments or lab test frequency, depending on whether a specific service code was used to bill Medicare services. Two large databases include measures of disability, pain, and treatment side effects, but their representativeness needs to be confirmed. The Arthritis, Rheumatism, and Aging Medical Information System, funded by the National Institutes of Health and managed by the Department of Rheumatology at Stanford University, has clinical data from patients in selected U.S. and Canadian locations. The National Databank for Rheumatic Diseases, an independent research data bank for studying arthritis and rheumatic conditions, includes data on several thousand patients who volunteered to participate in the project. Because the data sets gather information on patients over time, patient follow-up techniques and dropout rates are key to assessing any potential biases of the patient samples, such as underrepresentation of less educated or minority patients.

Patients with infections

Medicare patients with infections (such as wound infections, bone infections, and endocarditis) may be infused with drugs or biologics according to a regimen that can span many weeks. For example, one treatment regimen for patients with bone infections calls for daily infusions for four weeks.

The Infectious Disease Society of America (IDSA) recommends that outpatient parenteral antimicrobial therapy (OPAT) programs track clinical and outcome measures (Tice et al. 2004). Quality measures for infectious disease could include whether the infection was successfully treated, whether the patient completed the course of treatment, vascular access complications (such as infections), and mortality rates. The IDSA practice guidelines on outpatient parenteral antimicrobial therapy include recommended frequencies of lab monitoring—another possible process measure. IDSA also recommends that programs evaluate how well they screen out high-risk patients who are not suitable for outpatient care. Comparing the shares of patients not suitable for outpatient therapy across practices could inform a practice about when it deviates from norms. In a separate guideline on catheter care, IDSA discusses the risks of infection and phlebitis associated with different insertion sites, the types and sizes of catheters, and the replacement and relocation of devices (O'Grady et al. 2002). The Infusion Nurses Society also has developed guidelines for inserting, maintaining, and caring for vascular access devices.

Medicare does not gather process or outcomes measures related to infusions. Some vascular access complications and mortality could be derived from claims data, but they could not be definitively linked to the infusion therapy. A national OPAT outcomes registry gathers outcomes

data from participating sites on several of the measures discussed above (including the clinical and bacterial status of the patient, whether the patient completed the course of treatment, vascular access complications, and survival status). As with the data sets previously discussed, the sample's representativeness would need to be confirmed before it could be used to evaluate the care provided to beneficiaries.

Erythroid growth factor monitoring

The Congressional mandate directed the Commission to analyze the effect of payment changes on quality of care for conditions that require physician-administered drugs. Given the varied treatments we examined, it is not surprising that we did not find a uniform set of quality measures. However, when measures do exist, Medicare data generally do not include information necessary to evaluate the quality of care.

In our Report to the Congress (2006) on oncology services, the Commission recommended that the Secretary require providers to enter patients' hemoglobin levels on all claims for erythroid growth factors. We said that the data should be used as part of Medicare's pay-for-performance initiative. Use of growth factor to treat anemia following chemotherapy has been increasing rapidly. At the same time, concerns have been raised about the safety of growth factors. In 2004, the Food and Drug Administration (FDA) responded to safety concerns by issuing new prescribing information. Although noting the need for individually based dosing, the agency recommended that the target hemoglobin level for cancer patients should not exceed 12 g/dL and that growth factor should be withheld if the hemoglobin level is 13 or higher.

Several recent studies have examined increased risks associated with use of growth factor at higher hemoglobin levels for patients on dialysis and for patients with chronic kidney disease (Cotter et al. 2006, Singh et al. 2006). A meta-analysis of 57 studies found that treating cancer patients with growth factor increased the risk of thromboembolism (Bohlius et al. 2006). The authors also suggested that growth factor may decrease survival rates.

These studies strengthen the need for Medicare to monitor hemoglobin levels for patients receiving erythroid growth factor. Some local carriers have limited the use of growth factor in accordance with FDA regulations and clinical guidelines. Carriers can use diagnosis codes to determine whether use of growth factor is warranted but they cannot tell whether the product is being used appropriately for specific patients without access to their medical records. Hemoglobin levels are variable. If the hemoglobin level is recorded on each claim, Medicare will be able to track whether it falls within the target range. In the case of dialysis patients who require these drugs, providers must enter the patient's hematocrit level on claims forms to ensure that patients are receiving appropriate care. Researchers would have more data available to measure the effect of the medications on quality of life and survival of cancer patients if the hemoglobin levels were on the claim form.

In the Tax Relief and Health Care Act of 2006, the Congress requires physicians to report patient hemoglobin levels when submitting claims for antianemia drugs for cancer patients.

Role of Part D

For patients without supplemental insurance, Part D creates another way to pay for drugs that may complement or substitute for drugs they receive in the doctor's office. With the exception of the rheumatoid arthritis drugs mentioned above, however, few physicians see Part D as interacting directly with coverage for the drugs they administer in the office. A few physicians we spoke with discussed having patients "brown bag" physician-administered drugs so that they would be covered under Part D. That is, instead of ordering a drug for shipment to the office, a physician could write a prescription and ask the patient to pick up the drug at the pharmacy. Practices raised several concerns with this idea. For drugs that need to be kept at a certain temperature or that have other specific storage requirements, doctors did not want to put the patient in charge of maintaining the proper storage environment. In addition, many pharmacies do not regularly stock some drugs, and waiting for them to acquire a drug could create problems with a patient's treatment schedule. However, some physicians who were unable to purchase key drugs at the Medicare payment rate were experimenting with this idea.

A few practices mentioned the possibility of having an on-site pharmacy to process prescriptions without direct patient involvement. That would solve issues of maintaining an adequate supply of drugs under appropriate conditions and would create a different option for drug reimbursement.

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Endnotes

1. As a point of comparison, from December 31, 2005, to March 31, 2006, prices for the most widely used brand name outpatient drugs increased by 3.9 percent (AARP 2006). The general inflation rate during this period was 1.1 percent.

2. Our measure of drug volume includes drug mix (or intensity). When newer more expensive therapies substitute for older, cheaper drugs, the result is considered an increase in volume.

3. For further detail on practice changes made by oncologists see MedPAC (2006).

4. Because this analysis is based on a 5 percent sample of beneficiaries, a cutoff of $20,000 amounts to physicians with expected revenues for drugs of $400,000 if inflated to reflect all claims. Since the analysis was done on a 5 percent sample of beneficiaries, not physicians, inferences about physician behavior must be treated as suggestive.

5. None of the urologists that we interviewed had begun sending patients to the hospital outpatient department.

APPENDIX A

Mandate for report

Mandate for report

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 303

(5) (A) REVIEW.—The Medicare Payment Advisory Commission shall review the payment changes made under this section insofar as they affect payment under part B of title XVIII of the Social Security Act—

i. For items and services furnished by oncologists; and
ii. For drug administration services furnished by other specialists.

(B) OTHER MATTERS STUDIED.—In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect—

i. The quality of care furnished to individuals enrolled in part B and the satisfaction of such individuals with that care;
ii. The adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and
iii. The impact on physician practices.

(C) REPORTS.—The Commission shall submit to the Secretary and Congress—

i. Not later than January 1, 2006, a report on the review conducted under subparagraph (A) (i), and
ii. Not later than January 1, 2007, a report on the review conducted under subparagraph (A) (ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

APPENDIX B

Commissioners' voting on recommendations

Commissioners' voting on recommendations

In the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation, and to document the voting record in its report. The information below satisfies that mandate.

Recommendation

The Secretary should clarify average sales price (ASP) reporting requirements for bundled products to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.

Yes: *Behroozi, Bertko, Borman, Burke, Castellanos, Crosson, DeParle, Durenberger, Hackbarth, Hansen, Holtz-Eakin, Kane, Milstein, Muller, Reischauer, Scanlon, Wolter*

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