JANUARY 2006

REPORT TO THE CONGRESS

Effects of Medicare Payment Changes on Oncology Services

MEDPAC Medicare Payment Advisory Commission

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Executive summary

Executive summary

In 2005, Medicare implemented significant changes in the way it pays oncologists for physician-administered drugs and drug administration services. Congress mandated that the Commission evaluate the effect of these changes and make policy recommendations if appropriate. We found that the payment changes did not affect beneficiary access to chemotherapy services. Some shifts in site of service were reported in site visits. Physicians provided more chemotherapy services and more Medicare beneficiaries received services in 2005 than in 2004. We saw no indication that quality of care was affected, and patients continue to be satisfied with the care they are receiving. Although the use of chemotherapy services varied by geographic region, we found no indication of access problems in any region. In general, larger practices were able to purchase chemotherapy drugs at lower prices than smaller practices, but all could buy most drugs at prices below the Medicare payment rate.

The Commission analyzed the effects of the payment changes on the provision of chemotherapy services through a series of studies:

- We analyzed expenditures and changes in volume for chemotherapy services using Medicare claims data.
- We analyzed a commercial database with prices for drugs used by oncologists to see if prices physicians paid were below the Medicare payment rates, and we measured the variation in prices different physician practices paid.
- We visited community oncologists, hospital outpatient departments, and health plans in five markets to discuss the effects of payment changes on practices.
- We conducted four focus groups with Medicare beneficiaries receiving chemotherapy in the past year to see how the payment changes affected their experiences.
- We interviewed stakeholders to gain their perspective on how the 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 chemotherapy.

The Congress asked us to analyze the effects of the payment changes on a number of issues:

How did the payment changes affect Medicare payments?

Following historical trends, the Commission found that use of chemotherapy drug administration services and chemotherapy drugs increased in 2004 and 2005 following Medicare payment changes. Oncologists provided more chemotherapy sessions to Medicare beneficiaries in 2005 than in the previous year, and more individuals received chemotherapy in physician offices.

After the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) mandated payment increases in 2004, Medicare 2005 total payments for drug administration services equaled 2004 levels, but the volume of services provided to Medicare beneficiaries increased. Medicare paid less for chemotherapy drugs in 2005 than the previous year, although the volume of drugs provided to beneficiaries, measured by quantity and drug mix, increased. The mix of chemotherapy drugs provided to beneficiaries shifted towards newer, more expensive agents. Volume and spending for erythroid growth factors continued to increase.

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

Our ability to assess the quality of chemotherapy-related services received by Medicare beneficiaries is limited. Few consensus quality indicators for chemotherapy exist, although the profession is working to develop them. Beneficiaries in our focus groups reported that they were satisfied with the quality of care they received.

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

Overall trends in spending for chemotherapy drugs and drug administration services were similar in all geographic areas. Consistent with the general increases in chemotherapy services, the Commission found no evidence of access problems for Medicare beneficiaries needing chemotherapy in any part of the country. However, beneficiaries without supplemental coverage may be more likely than other beneficiaries to receive chemotherapy in hospital outpatient departments in some areas.

How did the payment changes affect adequacy of payment and availability of chemotherapy services in different practice sizes?

We were unable to collect empirical data on this subject. Based on its audit of physician purchases of chemotherapy drugs, the Office of Inspector General (OIG) of the Department of Health and Human Services found that large practices generally could get lower prices for drug purchases. However, all practices could purchase most drugs at or below the Medicare payment rate. During our site visits, we also determined that physicians in varied practice settings were able to purchase most drugs at the Medicare payment rate.

What was the impact on physician practices?

Our site visits suggest that all physician practices considered the 2005 payment changes significant and that they made changes in response to the new payment system. Oncologists responded to the changes by cutting costs and increasing efficiency (particularly with respect to drug purchasing activities), finding new sources of revenue (such as imaging) or selecting more profitable patients. Many physicians reported that the payments furnished to them through the quality-of-life demonstration project implemented by the Centers for Medicare & Medicaid Services (CMS) in 2005 ensured that they continued to provide care to Medicare beneficiaries,

although they did not believe that the project would improve quality or produce useful research results. The payments CMS provided to oncologists through this project made it difficult for the Commission and the Congress to evaluate the effect of the Medicare payment changes.

The Commission recommends some policy changes to improve the payment system and promote beneficiary access and quality chemotherapy care.

Recommendations are:

RECOMMENDATION 1

The Secretary should allow an exception to the competitive acquisition program (CAP) delivery rules for rural satellite offices of providers.

RECOMMENDATION 2

The Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments.

RECOMMENDATION 3

The Secretary should require providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

The Commission would have recommended that OIG conduct another study of physician purchase prices for chemotherapy drugs. However, OIG has announced plans to conduct audits of drug acquisition costs for additional practices in 2006. Also, in the course of this study and an earlier one on cost sharing in private plans serving Medicare (MedPAC 2004), the Commission recognized that beneficiaries receiving chemotherapy could be liable for very high cost sharing. Changes to the Medicare benefit design that would limit cost-sharing liability for cancer patients and other patients with large health care spending merit further study.

Effects of Medicare payment changes on oncology services

RECOMMENDATIONS

1 The Secretary should allow an exception to the competitive acquisition program (CAP) delivery rules for rural satellite offices of providers.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

2 The Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments.

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3 The Secretary should require providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Medicare payment changes

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) changed the way Medicare pays for both covered outpatient drugs and drug administration services under the physician fee schedule.[1] The Congress directed the Commission to study the effects of these changes on the quality of care Medicare beneficiaries received, patient satisfaction with that care, the adequacy of payments in different geographic areas and physician practice sizes, and the impact on physician practices (Appendix A). The first report, due January 1, 2006, focuses on services provided by oncologists; the second report, due January 1, 2007, focuses on drug administration services provided by other specialists.

Before 2003, Medicare generally paid physicians at rates well above their acquisition costs for physician-administered drugs but paid less for the costs involved in administering those drugs (MedPAC 2003). In 2004, the MMA reduced payment for most covered drugs from 95 percent of the average wholesale price (AWP) to 85 percent of the listed AWP as of April 1, 2003. Since AWP did not reflect actual prices charged to purchasers, the payment reduction resulted in payments that were still generally above acquisition costs (see MedPAC 2003 for discussion of incentives created by AWP). Medicare increased payment for drug administration services, particularly those used for chemotherapy. In addition, the MMA mandated two years of transition payments for chemotherapy drug administration services. This means that after CMS calculated new drug administration rates, it added transition payments each time a drug administration code was billed. In 2004, CMS increased each payment by 32 percent, and in 2005 each payment was increased by 3 percent.

In 2005, payments for drugs and drug administration services changed again. The MMA set payments for covered drugs at 106 percent of the average sales price (ASP).[2] ASP is based on actual transaction prices. In addition, CMS established new drug administration codes but reduced transition payments for drug administration services from 32 to 3 percent. As a result, physicians saw lower fees for individual drug administration services than in 2004, but they could bill for more services during each chemotherapy session.

CMS also implemented a one-year demonstration project to evaluate how chemotherapy affects the level of fatigue, nausea, and pain experienced by patients. All oncologists were eligible to receive $130 per patient per day for asking chemotherapy patients three questions about how they had responded to treatment. Answers were coded on a 4-point scale, and each answer had a payment code attached. To receive the payment, physicians had to submit answers to all three questions.

In 2006, some additional payment changes will take place. Physicians no longer will receive transition payments for drug administration services. CMS substituted a different demonstration project for the 2005 quality-of-life project. The agency lowered payments for this demonstration and changed data requirements. Physicians will be eligible to receive the demonstration payments in connection with oncology evaluation and management visits by cancer patients.[3]

The MMA calls for the establishment of a competitive acquisition program (CAP) in 2006. Organizations such as wholesalers or specialty pharmacies would submit bids to Medicare

to become designated vendors for Part B drugs. Each year, physicians would choose whether to continue to purchase and bill for Part B drugs or receive these drugs through a Medicare-designated vendor. Vendors would purchase and dispense drugs to physician offices on the basis of prescriptions written by physicians for their Medicare patients. Medicare would pay the vendors directly and the vendors would bill patients for required copayments. The program has not yet been implemented. In recent rule making, CMS changed requirements for CAP vendors and expects to implement the program by July 2006.

MedPAC analyses

Because the legislated changes have not yet been fully implemented, the Commission has limited ability to analyze the impact of these changes. In addition, we have only partial Medicare claims data for 2005, the first year Medicare implemented a new pricing method based on the ASP. Information provided during our site visits is not necessarily generalizable, and the perspectives of beneficiaries and providers have not been separately validated. Finally, few consensus quality indicators exist for chemotherapy-related services, although the profession is working to develop them.

The Commission undertook a series of qualitative and quantitative analyses to examine the effect of Medicare payment changes on the delivery of oncology services to Medicare beneficiaries. We conducted site visits to oncology facilities in five regions of the country. We organized four focus groups of beneficiaries who had received chemotherapy within the past year. We analyzed Medicare claims data and drug pricing data. Additionally, we interviewed stakeholders involved in the purchase and distribution of chemotherapy drugs. Finally, we reviewed the literature on pricing for Part B drugs and studies of quality-of-care indicators for chemotherapy.

Site visits

In 2004 we conducted site visits in five states or metropolitan areas to learn how chemotherapy was delivered in different types of practices around the country. In some cases we focused on a single metropolitan area; in others we visited practices located throughout a state. We visited practices in northern New Jersey, Iowa, Seattle, Atlanta, and New Mexico. Although the opinions elicited during these visits were subjective and cannot be considered nationally representative, we found considerable consistency in physicians' perspectives. In physician offices, we met with oncologists, oncology nurses, practice administrators, and pharmacists. Although we focused on community oncology practices most affected by the payment changes, we also met with relevant personnel in community hospitals, university hospitals, and cancer hospitals. To obtain a broader perspective on market conditions for oncology services, we also met with representatives of local health plans.

Physician interviews included questions on:

- practice size and patient volume,

- patient mix, including percentage of Medicare patients,
- drug selection and purchasing practices,
- the impact of new (and very expensive) chemotherapy agents,
- shifts in site of service,
- services provided to cancer patients, and
- quality of care in different settings.

Oncologists who worked within hospitals described the extent to which their institutions delivered chemotherapy. We asked if they were experiencing any increase in volume as a result of patients being shifted from physician offices to hospital outpatient departments. Finally, we asked them to compare the quality of services provided in both settings.

Representatives of local health plans discussed the market for oncology services in their communities. They discussed their payment methods and how they expected to be affected by the Medicare payment changes.

In 2005, we conducted follow-up interviews. We asked practices to evaluate how the payment changes actually affected them. We also asked them about ways Medicare could measure and provide incentives for quality care of cancer patients.

Beneficiary focus groups

In 2005, we conducted four focus groups with Medicare beneficiaries who had received chemotherapy services within the past year. Focus groups took place in Georgia and Maryland. Beneficiaries who participated in our focus groups received treatment in a variety of settings, including single-specialty oncology offices, outpatient departments of community hospitals, outpatient departments within university hospital cancer centers, and infusion centers of integrated health plans. We asked beneficiaries to discuss their satisfaction with the services they had received and whether they had experienced any changes in their chemotherapy care during the past year.

Medicare claims analysis

We analyzed partial-year carrier claims for 2005 to see if current payment changes had an impact on volume and spending for chemotherapy services provided within physician offices. We also analyzed Medicare claims data from 1999 to 2004 to examine trends in use and spending for Medicare beneficiaries receiving chemotherapy. We analyzed spending for drugs and drug administration services.

For the period between 1999 and 2004, we wanted to see if any shift occurred in the site of care for chemotherapy services from physician offices to hospital outpatient departments. When the

MMA was passed, some oncologists said that they might send their Medicare patients to the hospital for chemotherapy rather than furnish the service in their offices. Currently, more than 80 percent of chemotherapy is provided in physician offices. A significant shift in site of care could create convenience or access problems for beneficiaries if hospitals do not have the capacity to meet higher demand or if beneficiaries must travel long distances to the hospital. In addition, costs are generally higher for beneficiaries and the Medicare program when chemotherapy is provided in hospitals. Beneficiaries without supplemental insurance and patients requiring expensive therapies could be particularly at risk for higher out-of-pocket costs if physicians began sending some of their patients to the hospital.

Drug pricing analysis

We purchased commercial data on prices for the top 20 Part B drugs used by oncologists from the last quarter of 2004 to the third quarter of 2005. Although these data do not include all the rebates that purchasers may receive from manufacturers, they allow us to look at price trends over time, variation in prices negotiated by different purchasers, and average prices obtained by different types of purchasers, such as hospitals and physicians.

Interviews with stakeholders

We interviewed wholesalers, specialized oncology group purchasing organizations, and pharmacists working at physician practices and hospitals to understand better how oncology drugs are sold and distributed. Interviewees talked about how the drug distribution system for Part B drugs has changed since Medicare began basing payment on the average sales price. We also interviewed representatives of oncology specialty societies to discuss indicators that Medicare could use to measure quality of care for chemotherapy patients.

Medicare spending on chemotherapy drugs and services

We measured changes in use and spending on chemotherapy drugs and drug administration services for Medicare beneficiaries from 1999 to 2004, the last year for which we have complete data. Beneficiaries received an increasing volume of drugs and drug administration services throughout the period. Physicians tended to substitute newer, more expensive medications for older products. For 2005, we have partial data for chemotherapy drugs, erythroid growth factor, quality-of-life demonstration payments, and payments for drug administration services provided in physician offices. From this limited data, we found that Medicare payments for chemotherapy drugs declined while payments for erythroid growth factors continued to increase. Medicare beneficiaries received more drug administration services, but Medicare expenditures remained at 2004 levels. We estimate that the Medicare quality-of-life demonstration added about $200 million in payments to providers.

Payment trends: 2000–2004

In this section, we analyze historical trends in spending for chemotherapy and drug administration services from 2000 to 2004, the last year for which we have complete data. We found that data present a consistent picture (Tables 1 and 2). Whether in the aggregate, by site of service, or by individual drug, Medicare expenditures for chemotherapy drugs and drug administration services increased during the period. Drug administration services include providing chemotherapy infusions, other infusions, and injections to cancer patients. A nurse usually provides these services. The drugs used for chemotherapy and other purposes are billed separately. We found that drug spending grew rapidly in the period before passage of the MMA. In 2004, the first year legislated changes took effect, trends changed. Expenditures for drug administration services increased 217 percent, while spending for chemotherapy drugs increased by 4 percent. In 2004, Medicare expenditures for medical oncology services totaled $7,312,000,000, an increase of 19 percent over 2003.[4]

In 2004, the largest increase was for chemotherapy administration, which increased by 217 percent, to $912 million. This increase resulted from the increases in payment rates for chemotherapy services mandated by the MMA and increased volume. Payments for drug administration services represented about 12 percent of all Medicare payments to oncologists in 2004 (Figure 1, p. 9).

In 2004, the MMA reduced the payment rate for most covered drugs. As a result, drug payments to oncologists grew more slowly than historical trends would indicate. Nevertheless, payments for anemia drugs increased 17 percent over 2003 (following a 51 percent increase in 2003). Payments for other drugs, used primarily to treat the side effects of chemotherapy, increased by 13 percent over 2003 levels.

Table 1

Medicare payments for medical oncology services, by type of service, 1999–2004

	Spending (millions)					
Type of service	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
All Part B drugs:	$1,645	$2,132	$2,674	$3,650	$4,790	$5,276
Chemotherapy drugs	870	1,092	1,350	1,736	2,199	2,298
Erythroid growth factor	321	457	642	854	1,291	1,511
Other drugs	453	583	683	1,060	1,300	1,468
Drug administration	180	206	230	238	288	912
E&M services	550	612	676	745	823	862
Other services	136	151	174	213	256	260
Total	**2,512**	**3,102**	**3,754**	**4,845**	**6,157**	**7,312**

Note: E&M (evaluation and management). Medical specialties defined as hematology, hematology/oncology, and medical oncology. Other services include tests, imaging, and other procedures.

Source: Direct Research analysis of data from Medicare Physician/Supplier Procedure Summary Master File, 1999–2004, and OPPS Files, 2004 Final Rule through 2006 Proposed Rule.

Table 2

Annual growth rate in Medicare payments for oncology services, by type of service, 1999–2004

	Annual growth (percent)				
Type of service	**2000**	**2001**	**2002**	**2003**	**2004**
All Part B drugs	30%	25%	36%	31%	10%
Chemotherapy drugs	25	24	29	27	4
Erythroid growth factor	42	40	33	51	17
Other drugs	29	17	55	23	13
Drug administration	14	11	3	21	217
E&M services	11	10	10	11	5
Other services	11	15	22	21	2

Note: E&M (evaluation and management). Medical specialties defined as hematology, hematology/oncology, and medical oncology. Other services include tests, imaging, and other procedures.

Source: Direct Research analysis of data from Medicare Physician/Supplier Procedure Summary Master File, 2000–2004, and OPPS Files, 2004 Final Rule through 2006 Proposed Rule.

Payments for evaluation and management (E&M) services provided by physicians increased 5 percent, and payments for other services, including imaging and tests, increased 2 percent over 2003 levels.

Medicare spending for drugs and drug administration in 2005

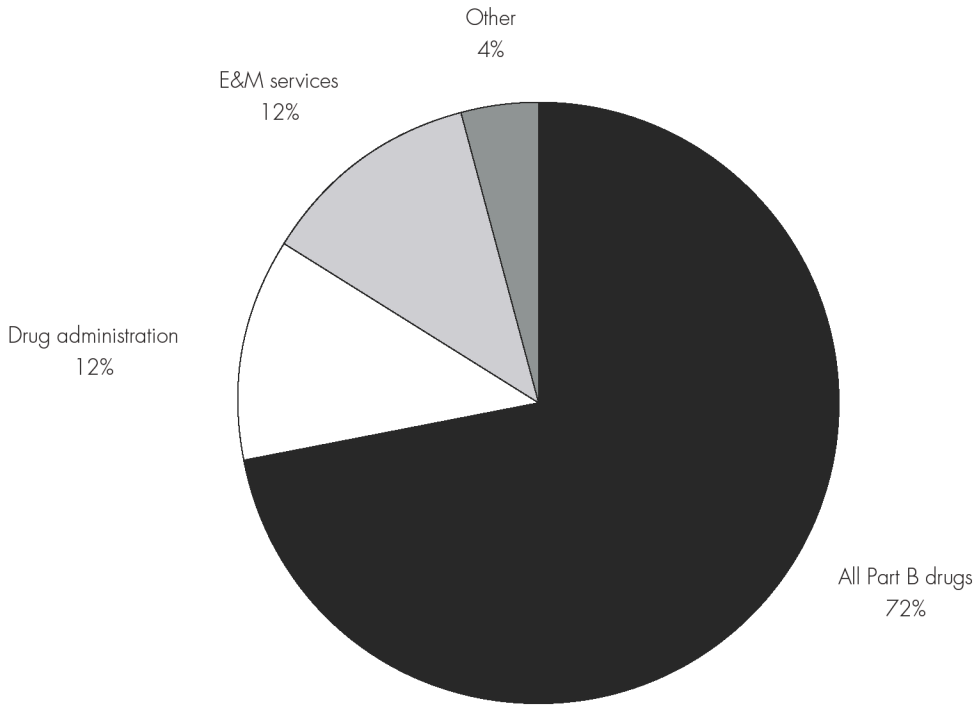
To measure the impact of 2005 Medicare payment changes, we analyzed carrier claims for the first six months of 2005.[5] We compared our results to spending and volume claims for the same period in 2003 and 2004. The data cover drug administration services, chemotherapy drugs, and erythroid growth factor used to treat anemia, administered in physician offices.[6] We also have spending data for the quality-of-life demonstration project funded by CMS in 2005. We do not have data on use and spending for other drugs to treat the side effects of chemotherapy or for other physician services provided by oncologists. We found that beneficiaries received more drug administration services in 2005 than 2004 but spending remained constant. Medicare payments for chemotherapy drugs declined in 2005. Physicians substituted newer, more expensive chemotherapy drugs for older drugs. Use and spending for erythroid growth factors continued to increase. We estimate that the demonstration project will add about $200 million to spending for chemotherapy services.

Drug administration services

- Coding changes make comparison of drug administration services between 2003, 2004, and 2005 difficult. The Congress added 32 percent transition payments for drug administration

Figure 1

Medicare payments to oncologists, by type of service, 2004



Note: E&M (evaluation and management). Medical specialties defined as hematology, hematology/oncology, and medical oncology. Other services include tests, imaging, and other procedures.

Source: Direct Research analysis of data from Medicare Physician/Supplier Procedure Summary Master File, 1999–2004, and OPPS Files, 2004 Final Rule through 2006 Proposed Rule.

in 2004 and 3 percent transition payments in 2005. Also in 2005, CMS established new codes that permit physicians to bill more codes for an individual chemotherapy session. The total number of chemotherapy drug administration services increased 33 percent from 2003 to 2005, while spending increased 182 percent.

- To measure the number of chemotherapy infusions provided in physician offices, we compared only the initial infusion code billed when chemotherapy sessions began in 2004 and 2005. Using this metric, we estimate that physicians provided 13 percent more chemotherapy infusion sessions in 2005 than in 2004.

- We also compared the number of Medicare beneficiaries receiving chemotherapy in physician offices in 2003, 2004, and 2005. This analysis was complicated because of inconsistencies in the claims data. We found many instances of chemotherapy administration codes billed without any accompanying drug claims. We also found claims for chemotherapy drugs without any accompanying drug administration claims. We estimate that the number of beneficiaries receiving chemotherapy increased 7.5 percent in

2005, based on the most conservative assumption. No matter what set of assumptions we used, Medicare beneficiaries received an increasing number of chemotherapy sessions in physician offices from 2003 to 2005.

Chemotherapy drugs

- Medicare paid less for chemotherapy drugs in 2005 than in 2004, although the volume of drugs provided to beneficiaries, measured by quantity and drug mix, increased (Table B-1, p. 41). As in previous years, physicians tended to substitute newer, more expensive drugs for older products (Table B-2, p. 42). Expenditures for chemotherapy drugs declined by 14 percent from 2004 levels.

Erythroid growth factors

- Compared to 2004, the use of erythroid growth factors grew 15 percent in 2005 when measured in equivalent doses between agents. We found that total spending for these products, unlike chemotherapy drugs, grew 3 percent.

Quality of life demonstration project

- In 2005, CMS implemented a demonstration project that paid oncologists to report on the side effects of chemotherapy their patients had experienced. In the part-year file through June 23, 2005, CMS had paid for almost 1.9 million assessments, at a cost of about $81 million. Assuming no trend, extrapolating that amount to the entire year would suggest that CMS will pay about $200 million under this demonstration in 2005.[7]

Changes in physician practices

The Congress required the Commission to examine the effect of the payment changes to physician practices. During our site visits, we asked physicians for their response to the Medicare payment changes. Although their answers were subjective, physicians told us they considered the payment changes significant and changed their practices in response. All practices changed their drug purchasing activities. Some also changed their use of drugs, office staffing, mix of services offered, and patient mix.

All the physicians we visited reported that they spent more time and resources shopping for lower prices for drugs than they did before the payment changes. Their choice of ancillary drugs for treating chemotherapy side effects was more likely to be based on price. Many practice managers reported that they routinely purchased only one drug to treat nausea and one erythroid growth factor to treat anemia for all the physicians in the practice. Physicians also reported that they kept smaller inventories of drugs on hand than previously. This allowed them to respond quickly to price changes and avoid tying up large sums of capital.

Many offices have hired employees to work with patients when they begin treatment to ensure that they can pay their out-of-pocket expenses. This financial adviser estimates the beneficiary's potential liability based upon the treatment plan. If the beneficiary does not have supplemental insurance, the adviser determines whether she qualifies for other assistance, including Medicaid and assistance programs maintained by individual pharmaceutical manufacturers. The beneficiary may be given a payment schedule to make copayments over time.

Practices reported that differences in local coverage policies affected their treatment decisions. Physicians were reluctant to use expensive new therapies that they thought the local carrier might not cover. For example, a carrier might cover a new drug for treatment of one cancer while the physician wanted to use it to treat a patient with another type of cancer. One practice reported sending a patient to the hospital outpatient department for treatment because the local intermediary covered a particular drug and the carrier did not. Practices reported they were less likely to appeal local coverage decisions. They found the appeals process too expensive and time-consuming and the outcome of the appeal uncertain.

Physicians also took actions to reduce costs or improve efficiency. For example, some practices reduced costs by changing their mix of employees, replacing full-time employees with part-time employees, or replacing nurses with pharmacy technicians. Similarly, many practices reported that they reduced health and pension benefits for their employees. One practice reported increasing efficiency by hiring workers to do the coding for oncology nurses. In this way, they believed that more of the nurses' time would be freed for patient care. Similarly, several practices reported hiring a pharmacist to purchase and mix drugs. The pharmacist also recommended drugs to the practice based on price and clinical effectiveness.

Some practices tried to increase revenues by providing more services in their offices. For example, some physician practices purchased positron emission tomography (PET) scanning technology in the past few years and increased imaging in their offices. However, this was only possible for practices with large facilities. Many practices reported they did not have the space or capital to expand in this way.

No physician or office manager reported that the payment changes affected the quality of care in their office. No beneficiary who participated in our focus groups reported that she had seen a decline in the quality of care she was receiving.

Geographic differences

As with other medical services, the volume of chemotherapy drugs and drug administration services provided to Medicare beneficiaries varies considerably by area. Overall trends in spending for chemotherapy drugs and drug administration services were similar in all geographic areas. We found no evidence of access problems for Medicare beneficiaries needing chemotherapy in any part of the country, although beneficiaries without supplemental coverage did get their chemotherapy in the hospital more often in some areas.

Physicians practicing in low geographic practice cost index (GPCI) areas told us they faced disproportionate cuts in their overall payments because of the Medicare payment changes. Unlike drug administration services, payments for drugs are not adjusted for geographic variation in the costs of practice. With the MMA payment changes, physicians in these areas saw the same cuts in payments for chemotherapy drugs but received lower additional payments for drug administration services than physicians in other parts of the country.

Some physicians faced unique state laws and regulations that affected their Medicare payments. For example, some states impose taxes on the drugs physicians purchase. State Medicaid policies also affected the payments physicians received for treating beneficiaries dually eligible for Medicare and Medicaid. In many states, Medicare program payments for services (80 percent of the allowed payment rate) are equal to or higher than Medicaid rates. In these instances, the state Medicaid program may not pay the 20 percent copayment for dual eligibles. Providers receive the Medicare payment as payment in full.

Beneficiaries without supplemental insurance

Prices for new cancer and other Part B drugs have increased rapidly, while Medicare has begun to pay physicians close-to-acquisition costs for drugs. Beneficiary copayments (20 percent of the payment) have been rising, and physicians who cannot collect coinsurance from beneficiaries will receive only 80 percent of the Medicare payment rate for the drugs. There is no limit to the out-of-pocket costs that beneficiaries may face. Medicare beneficiaries without supplemental coverage may be transferred to hospital outpatient departments (HOPDs) and face higher copayments there. However, if beneficiaries who cannot pay cost sharing in physician offices go to HOPDs for chemotherapy infusion, they are unlikely to be able to pay cost sharing there. Instead, their unpaid bills would become bad debt. Medicare pays 70 percent of hospitals' bad debt.

The Commission is concerned about the burden of cost sharing for beneficiaries with cancer and other catastrophic conditions. The Commission will explore the general issue of unlimited beneficiary out-of-pocket liability, which can affect cancer patients and patients with other illnesses, in future work.

Although we did not find any cases in which beneficiaries could not get chemotherapy services, Medicare beneficiaries without supplemental insurance have more limited choices in some areas of the country. These individuals are more likely than other beneficiaries to receive chemotherapy in HOPDs. In 2004, the Commission found that in some markets, oncology practices had stopped treating Medicare patients without supplemental insurance in their offices. Patients were sent to hospital outpatient departments or safety-net facilities. When we returned to these practices in 2005, we found they were sending an increasing number of patients to the HOPD.[8]

When patients are sent to the hospital for chemotherapy, the physician continues to manage their care. Physicians still provide evaluation and management visits, some lab work, and

other services in the office setting. Although quality of care may be equivalent in hospitals and physician offices, beneficiaries face higher copayments in HOPDs and treatment usually takes longer. For example, chemotherapy drugs must be mixed in the hospital pharmacy, where pharmacists are preparing medications for all the other hospital patients. The chemotherapy patient will wait longer until the medication is prepared. Only a few beneficiaries who participated in our focus groups had been referred to the HOPD from physician offices. They emphasized the duplication of tests and increased time commitments caused by the switch. One individual complained about the higher copayments.

As the price of new cancer drugs continues to rise, beneficiaries without supplemental insurance may have an increasingly hard time paying their 20 percent coinsurance. Although most physician practices have continued to treat all beneficiaries in their offices, beneficiary inability to meet cost-sharing requirements creates a financial liability for the practices. Unlike hospitals, physicians cannot receive payment for bad debt from Medicare. Many practices have begun to counsel beneficiaries on their estimated out-of-pocket liabilities before treatment begins. A few practices reported instances in which a beneficiary refused treatment because she did not want to travel to a hospital or leave her family with debts caused by her out-of-pocket liability.

We cannot quantify the number of beneficiaries who need help paying their coinsurance for chemotherapy. We have no source of data to determine the number of Medicare beneficiaries without supplemental insurance who are receiving chemotherapy services. Data on supplemental insurance are not captured on Medicare claims. The oncology practices we visited estimated between 5 and 20 percent of their Medicare patients have no source of supplemental coverage. Estimates varied depending on the demographic structure of the market and the availability of Medicare Advantage and retiree health insurance. The Commission (MedPAC 2005a) estimates that 9 percent of all beneficiaries have no source of supplemental coverage. Beneficiaries without supplemental coverage are not the only individuals facing high copayments. Some cancer patients who participated in beneficiary focus groups were concerned that they might exceed lifetime caps on their retiree coverage.

Many pharmaceutical companies offer patient assistance programs to help patients with the cost of their medications. In 2003, pharmaceutical companies provided patients with medications valued at $3.3 million. However, this assistance is not readily available for Medicare beneficiaries without supplemental insurance. Most of the assistance goes to patients without any insurance. Less aid is available for individuals needing help with copayments. Yet this cost may be beyond the means of many beneficiaries. For example, one new cancer drug costs Medicare an average of $12,000 every two weeks. Beneficiaries face copayments of $2,400 monthly for this medication. Beneficiaries continue taking the medication until their condition worsens. Medicare beneficiaries have no limit on the out-of-pocket drug costs they face under Part B, unlike Part D.

Additionally, manufacturers have individual programs linked to their own products. Chemotherapy regimens generally require administration of a number of different drugs. A patient would have to apply for assistance from each manufacturer. Therapies might be determined depending on which manufacturer programs are available for the patient.

In the case of chemotherapy drugs, physicians often find patient assistance programs difficult to

use, because the programs provide replacement drugs for products that have been administered rather than paying for the cost of the drug. Physicians cannot recoup the cost of the drug and cannot bill for the replacement product if they administer it to another patient because the physician did not buy it. Additionally, the physician may not have another patient who needs the specific medication.

Limited help is available for Medicare beneficiaries who need assistance paying out-of-pocket expenses. The Patient Advocacy Foundation, a national 501(c)(3) nonprofit organization, has established a Co-Pay Relief (CPR) program to help qualified insured individuals with copayments. The program is limited to patients who need treatment for breast cancer, lung cancer, prostate cancer, and macular degeneration.

The Commission is concerned about high cost sharing for cancer patients. The issue of unlimited beneficiary liability also affects other beneficiaries. In future work, we will examine long-term solutions to this problem.

Drug pricing in 2005

Medicare began paying for Part B drugs according to a new methodology, based on ASP, in 2005. Payment for most covered drugs is set at 106 percent of ASP. To date, this system has reduced payment rates for most covered drugs. In the course of our site visits, the Commission found that most oncologists could purchase most drugs at rates below the Medicare payment level, but profit margins on these drugs generally were low, as the policy change anticipated. Every practice reported that that they could not buy some drugs at the payment rate. A study by the Office of Inspector General (OIG), Department of Health and Human Services indicated that oncologists could still purchase most drugs at rates below the payment level, although specific drugs posed a problem for some practices. In general, larger practices paid lower prices than smaller practices for the same drugs.

The Commission has found that variation in prices paid by different purchasers has narrowed throughout 2005. In general, the Commission finds that the payment system for drugs is providing adequate payments, but some adjustments to the methodology may be warranted as Medicare gains more experience with the new system. We found that more far-reaching changes are needed in the regulations establishing the competitive acquisition program, an alternative payment system.

Average sales price methodology

In general, Medicare's change to a payment system based on ASP has resulted in program savings, and oncologists can purchase most drugs at prices below the payment rate. Although not an actual price, ASP represents the weighted average of the manufacturer's sales price for each product that falls within a Medicare drug billing code.[9] It is based on data submitted quarterly by pharmaceutical manufacturers, is net of price concessions such as rebates and

discounts, and is limited to sales in the United States. The ASP payment rate is set prospectively, based on transaction prices from two quarters prior.

All stakeholders that take part in the drug distribution system, including CMS, pharmaceutical manufacturers, group purchasing organizations (GPOs), and physician purchasers, have been affected by the new payment system. Stakeholders have had to adapt to the transition to the new system:

- CMS had to develop a new payment system and provide direction to manufacturers on calculating ASP for their products.
- Manufacturers had to evaluate their pricing practices with the knowledge that large discounts given to some purchasers would lower Medicare payment rates in subsequent quarters. If they raised prices sharply, they might reduce demand for their products. They also had to evaluate the fees they paid to wholesalers and GPOs. Representatives of GPOs told us they had more difficulty negotiating substantial discounts for their clients as manufacturers calculated the effect of reduced prices on their products' ASP for the following quarters.
- Oncology practices also had to adapt to the new system, developing more efficient purchasing practices. Many oncology practices interviewed noted they were more likely to purchase non-chemotherapy drugs on the basis of price than in previous years. All practices reported they kept smaller drug inventories, taking advantage of prompt pay discounts, the most readily available discounts they could receive under the new payment system.

Although rates calculated under the new system generally resulted in Medicare payments that were adequate, all physicians interviewed reported some drugs could not be purchased at the calculated rate. In conversations with the Commission staff, physicians frequently listed older generic drugs among the products they could not purchase at 106 percent of ASP. Wholesaler markups are not included in manufacturer ASP calculations but raise prices paid by physicians and other purchasers. If markups represent a higher percentage of the cost of generic drugs, they may result in inadequate payments for these products. Manufacturers also do not take into account final prices when products are resold by the original purchasers for profit.

How did the change to ASP affect Medicare payment rates for drugs?

A report issued by OIG (2005) found that oncologists generally could purchase drugs for the treatment of cancer at less than the Medicare payment rates (Table 3). The Congress mandated that OIG analyze acquisition costs for oncology drugs during the first quarter of 2005. The study was based on audits of 193 practices, focusing on payment for 40 drugs that in sum represented about 94 percent of total 2004 oncology-billed Medicare drug spending. The drugs included the 25 drugs with the highest total spending in 2004, five drugs identified by industry as having Medicare payment rates that were too low, and an additional 10 drugs with high expenditures. One drug, denileukin diftitox, was eliminated from the study because of insufficient purchases by sample practices.[10] Prices were collected from January through March 2005 and compared with Medicare payment rates for the first quarter of the year.

OIG estimated that, on average, practices could purchase 35 of the 39 drugs at less than the Medicare payment rate. For 32 of the drugs, OIG determined that average purchase prices were within 15 percent of the Medicare payment rate. Five of the 35 drugs had positive margins ranging from about 39 to 87 percent. Medicare paid practices at rates of 29 and 25 percent below cost for two drugs. On average, larger physician practices purchased drugs at lower prices than smaller practices. The smallest practices in the sample purchased 33 of the 39 drugs at prices below Medicare payment rates.

The Commission further analyzed the data presented in the OIG report to determine what kinds of drugs provided higher or lower payment margins compared to the Medicare payment rates (Table 3). We also examined what happened to the Medicare payment rate in the last quarter of 2005 for drugs with larger-than-average margins in the first quarter.

We found that the physicians were able to purchase drugs at rates well below the Medicare payment rate when generic alternatives, such as carboplatin and cisplatin, were newly available. Medicare payment rates for these drugs dropped sharply by October 2005. Purchasers also were able to buy brand name drugs with therapeutic substitutes available at prices well below Medicare payment rates. One example would be dolasetron mesylate, used to treat nausea in chemotherapy patients. In general, we found that when OIG found that the average purchase price for a drug was more than 15 percent lower than the January Medicare payment rate, the Medicare payment rate fell by October. Payment rates for chemotherapy drugs in this category declined from 72 to 38 percent.

OIG determined that, on average, Medicare payment rates were inadequate to meet provider costs for four drugs used frequently by oncologists. One possible reason for Medicare payments falling below acquisition costs could be the way manufacturers include rebates in their calculations of ASP. Since manufacturers frequently determine rebates retrospectively, based on the volume of sales to specific purchasers, they may not know the final price they received for a given drug at the end of a quarter. If a manufacturer reports the rebates earned by customers for a product throughout the year at the time when the rebate is actually paid, the price or ASP for the product will be lower than the typical acquisition cost for a purchaser during that reporting period. Since the first quarter of 2005, CMS has changed the way rebates are factored into ASP calculations. The agency found that some payment rates changed quarterly as the level of rebates added to the calculations fluctuated. This may have affected rates for some of the drugs listed here.

The OIG report was based on provider acquisition costs in the first quarter of 2005. In that quarter, ASP was calculated based on manufacturer prices in effect before the payment system changed. The report provided an early indication that Medicare payment rates under the ASP system were adequate. A second analysis is warranted to evaluate how the system is working following a year's experience.

The Commission had intended to recommend that OIG analyze 2006 physician acquisition costs to see how accurate Medicare drug payments are following a year's experience with the new payment system. However, OIG has announced that it intends to audit a sample of oncology practices to compare their acquisition costs with the Medicare payment rate in 2006. The

Table 3

Estimated average prices for drugs purchased by oncologists

Drugs	OIG estimated average purchase price	1st quarter Medicare payment rate	Percentage difference	4th quarter Medicare payment rate	Change in payment rate between 1st and 4th quarters
Carboplatin	$16.24	$125.47	87.1%	$35.25	–71.9%
Dexamethasone	0.05	0.14	64.3	0.11	–21.4
Cisplatin	2.05	4.96	58.7	2.37	–52.2
Vinorelbine	35.71	69.09	48.3	42.83	–38.0
Dolasetron Mesylate	4.04	6.61	38.8	6.52	–1.36
Cyclophosphamide	2.03	2.34	13.2	2.12	–9.83
Epoetin alfa	9.20	10.60	13.2	9.22	–13.0
Filgrastim	245.46	282.41	13.1	279.57	–1.0
Darbepoetin alfa	15.61	17.72	11.9	15.06	–15.0
Fluorouracil	1.49	1.68	11.3	0.64	–61.9
Leucovorin	1.16	1.30	10.8	1.32	1.8
Palonosetron hydrochloride	16.38	18.23	10.1	17.99	–1.3
Granisetron hydrochloride	6.39	7.09	9.9	7.14	0.6
Vincristine	3.18	3.50	9.1	3.60	2.9
Pegfilgrastim	2,080.71	2,273.93	8.5	2,078.07	–8.6
Etoposide	0.46	0.49	6.1	0.49	0.0
Docetaxel	280.71	297.58	5.7	293.64	–1.3
Pamidronate disodium	56.50	59.06	4.3	40.63	–31.2
Gemcitabine hydrochloride	111.40	115.34	3.4	115.89	0.5
Fludarabine	263.12	272.10	3.3	262.87	–3.4
Bevacizumab	55.27	57.08	3.2	57.11	0.1
Zoledronic acid	192.95	198.39	2.7	200.03	0.8
Trastuzumab	51.80	52.99	2.2	54.39	2.7
Oxaliplatin	8.07	8.24	2.1	8.53	3.5
Irinotecan	123.00	125.58	2.1	126.92	1.1
Mitoxantrone	316.10	321.80	1.8	323.80	0.6
Doxorubicin J9001	353.30	359.63	1.8	364.53	1.4
Topotecan	730.88	739.69	1.2	763.80	3.3
Octreotide	84.40	85.39	1.2	87.31	2.3
Diphenhydramine	0.93	0.94	1.1	0.72	–23.4
Sargramostim	21.44	21.67	1.1	21.87	0.9
Amifostine	414.00	417.56	0.9	439.31	5.2
IVIG non-lyophil	56.25	56.72	0.8	56.30	–0.7
Fulvestrant	79.97	80.51	0.7	81.33	1.0
Rituxan	440.10	442.01	0.4	455.92	3.2
Paclitaxel	16.71	15.85	–5.4	13.33	–15.9
Leuprolide	279.34	253.13	–10.4	224.42	–11.4
Enoxaparin sodium	6.45	5.16	–25.0	5.45	5.6
Doxorubicin J9000	5.48	4.26	–28.6	5.84	37.0

Note: OIG (Office of Inspector General), IVIG (Intravenous immune globulin). Table excludes denileukin diftitox, which was listed in the Inspector General's report without an estimated price.

Source: Office of Inspector General 2005, and MedPAC analysis of CMS October 2005 Payment Allowance Limits for Medicare Part B Drugs.

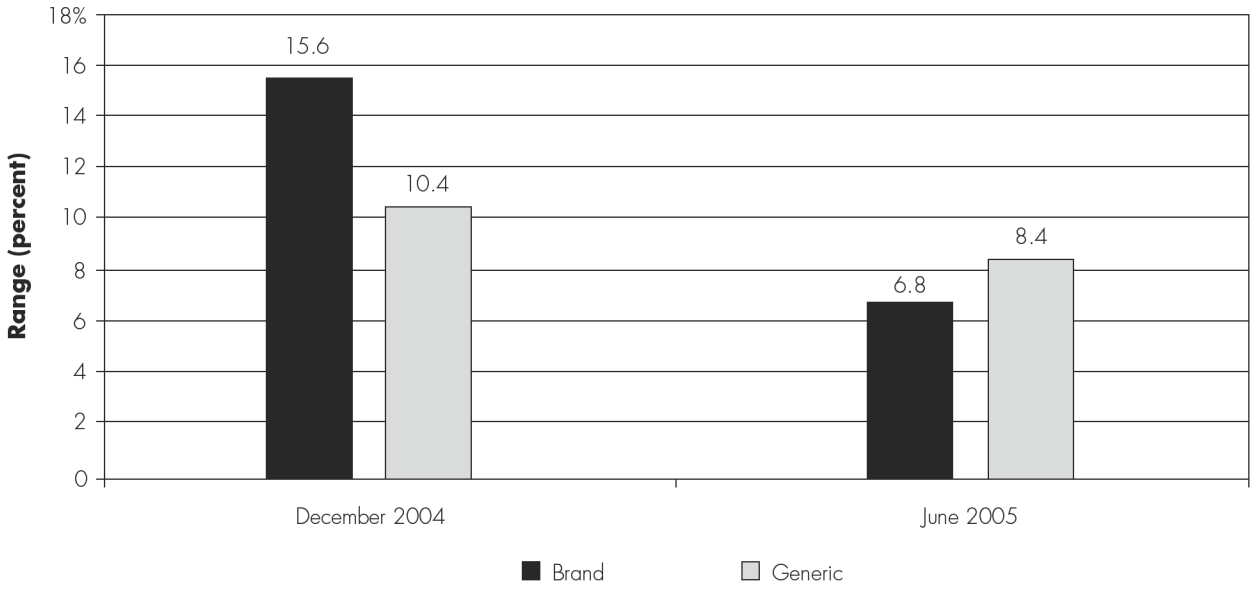
Commission also plans to monitor the relationship between ASP and purchaser prices in the coming year. If changes are warranted, we may recommend modifications to the calculation of ASP.

Price variation

The Commission hypothesized that pharmaceutical manufacturers would narrow the range of discounts offered to purchasers to ensure that all physicians could purchase their products at the Medicare payment rates. Since the market for chemotherapy drugs is limited, manufacturers would want to maximize their customer base. To track changes in oncology prices over time, the Commission acquired pricing information from a commercial data source.[11] The data track sales to retail pharmacies, staff-model HMOs, hospitals, clinics (including physician offices), long term care facilities, and federal facilities.[12] Prices are net of discounts but do not include rebates provided by manufacturers retrospectively. The database also shows variation between the lowest and highest prices the purchaser paid at each quartile for each distribution channel. The Commission purchased data on 26 drugs billed by oncologists for one month of each of the first

Figure 2

Change in price variation for selected brand and generic drugs purchased by oncologists



Note: Two drugs have been excluded because generic alternatives became available during the four quarters. Two others have been excluded because of crosswalk problems. The range measures the percent of variability among the prices paid by clinics. It is measured by subtracting the price paid by the 25th percentile of purchasers from the price paid by the 75th percentile of purchasers, dividing by the price paid by the 50th percentile of purchasers, and multiplying by 100. MedPAC's contract with IMS Health does not allow the prices of drugs to be named individually.

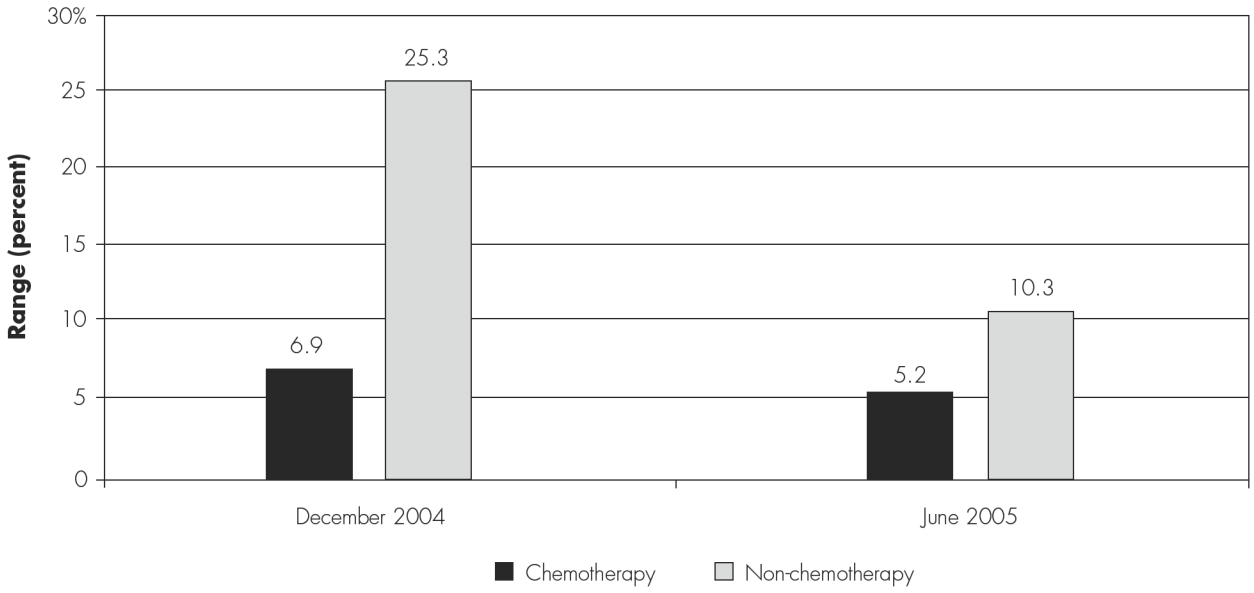
Source: MedPAC analysis of IMS Health data 2004–2005.

three quarters of 2005. Drugs include chemotherapy agents and medications used to treat the side effects of chemotherapy. Many overlap with the drugs identified in the OIG report. The 26 drugs accounted for more than 50 percent of physician-administered Part B drug spending in 2004.

Our analysis of prices paid by physicians showed that price variation for our basket of drugs declined between the first and third quarters of 2005. Next, we looked to see if the decline in price variation was more pronounced for any particular types of drugs. We grouped our drugs in two ways. First, we classified them based on whether they were single source branded drugs or had generic alternatives. Next, we looked at whether the drugs were chemotherapy agents or prescribed to treat the side effects of chemotherapy. For all four categories, the range, defined as the variation between the best and worst price obtained by physicians, narrowed between the first and third quarters of 2005.[13] The range for single source chemotherapy drugs—small to begin with—narrowed least, falling from 6.9 percent to 5.2 percent. The biggest change was in the range for drugs used to treat the side effects of chemotherapy. That range declined 54 percent in the third quarter (Figures 2 and 3).

Figure 3

Change in price variation for selected chemotherapy and non-chemotherapy drugs purchased by oncologists



Note: Two drugs have been excluded because generic alternatives became available during the four quarters. Two others have been excluded because of crosswalk problems. The range measures the percent of variability among the prices paid by clinics. It is measured by subtracting the price paid by the 25th percentile of purchasers from the price paid by the 75th percentile of purchasers, dividing by the price paid by the 50th percentile of purchasers, and multiplying by 100. MedPAC's contract with IMS Health does not allow the prices of drugs to be named individually.

Source: MedPAC analysis of IMS Health data 2004–2005.

Competitive acquisition program

The MMA mandated the establishment of a competitive acquisition program in 2006 as an alternative way for providers 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 unable to purchase drugs at the Medicare payment rate would have an alternative way of acquiring drugs and could continue to administer chemotherapy in their offices.

Under CAP, organizations like wholesalers or specialty pharmacies would submit bids to Medicare to become designated vendors for Part B drugs. Each year, physicians would choose whether to continue to purchase and bill for Part B drugs or to receive these drugs through a Medicare-designated vendor. Vendors would purchase and dispense drugs to physician offices on the basis of prescriptions written by physicians for their individual Medicare patients. Medicare would pay the vendors directly and the vendors would bill patients for required copayments. CMS delayed implementing this program in response to vendor and physician comments on the proposed rule. CMS issued an interim final rule on July 6, 2005, and a final rule on November 21, 2005.

None of the oncologists who we interviewed was willing to participate in CAP as described in CMS' interim final rule. Key criticisms of the rule by oncologists included the following:

- Vendors could stop supplying drugs for beneficiaries who did not pay their copayments in a timely fashion. If this happened, a beneficiary's treatment could end in the middle of a course of chemotherapy.
- Office administrative burden would increase. Physicians would have to write prescriptions for each patient's drugs, rather than purchasing drugs in bulk as required by the practice. There would be no payment to offset the administrative cost.
- Offices would have to maintain separate inventories for each patient covered through the CAP program.[14] If a patient could not receive treatment on a given day, as is frequently the case because of his medical condition, the office would have to return the drug to the vendor.
- Offices would be tied to a specific vendor for a year, even if they were not satisfied with the vendor's performance.
- Physicians would have to appeal all claim denials, even if they did not believe the time and effort required to mount the appeal constituted an effective use of practice resources.
- Physicians with satellite offices in rural areas could not participate in the program because they often cannot accept drug deliveries and mix drugs in their satellite offices.

In the physician fee schedule final rule, CMS announced that it would permit vendors to subcontract with physicians to collect beneficiary copayments. This decision might make the CAP program a more attractive alternative for some physicians. Physician offices could receive some payment to offset the administrative costs of participating in this program. They would also be aware of when beneficiaries could not pay their copayments and might be able to intervene before vendors stopped supplying necessary drugs. For example, they could encourage beneficiaries to apply for Medicaid or other programs that provide assistance with the costs of drugs.

Vendors are also likely to favor this decision because they believe it would be difficult to collect copayments from beneficiaries who do not know them or know what services they provide.

Potential vendors objected to the proposed rule for the CAP program because they did not believe it established the conditions for a profitable business. They argued they could not negotiate discounts with manufacturers because CAP prices are included in calculations of ASP. Since vendors must supply almost all physician-administered drugs requested by physicians and cannot encourage use of any one drug over another, manufacturers have little incentive to give them discounts, even though they would purchase a large volume of drugs. CMS did not receive any vendor bids before it decided to delay implementing the program.

In an interim final rule issued November 2, 2005, CMS exempted CAP prices from calculations of ASP for a period of up to three years. The agency then will reevaluate this policy and its effect on Medicare payment rates for Part B drugs.

The CAP program in rural areas

The CAP rules require that drugs be delivered to the facility in which they will be administered. Oncologists in rural areas pointed out that they could not participate in the program because of this rule. Beneficiaries in rural areas tend to receive chemotherapy in satellite clinics. A group practice located in a central region provides chemotherapy services once or twice a week in small satellite clinics owned by the physicians or in cooperation with a community hospital. Sometimes the physicians see patients at these clinics but administer chemotherapy only in their central offices. In some cases, physicians and nurses travel up to four hours to see patients at the satellite clinics. Some practices reported that they lost money on the satellite clinics but consider it part of their mission in rural areas. In 2004, many physicians we interviewed said they might have to close these clinics because of the Medicare payment changes, but most remained open in 2005.

Sometimes nurses cannot mix drugs safely in these satellite offices because the office does not have the expensive equipment necessary for the safe handling of these toxic products. Nurses mix the drugs at the main facility and then travel to the satellite office to administer chemotherapy. Under these conditions, the practice cannot ensure anyone will be at the satellite office to accept delivery of a drug shipment, and staff working in the satellite office may not be able to mix the drugs even if they do receive them.

The CAP delivery rules were a response to concerns of potential vendors (Bassano 2005). Under the CAP system, physicians do not own the CAP drugs. Vendors maintain title until the product is administered. Vendors were concerned that they would be liable if the physician transported the drug and did not handle it properly. The safety and quality of the drug could be compromised.

These concerns are not unreasonable. Physicians and vendors must always ensure that these drugs are handled appropriately. Currently, many private payers have adopted systems of "brown bagging" for physician-administered drugs (MedPAC 2003). Vendors deliver drugs to the patient's home, and the patient is responsible for bringing the medication to the physician's office. Physicians have raised concerns about the safety of drugs shipped in this way. Unlike most patients, rural oncologists have experience storing drugs, preparing them, and transporting them safely to satellite offices. Liability issues should be minimal.

RECOMMENDATION 1

The Secretary should allow an exception to the competitive acquisition program (CAP) delivery rules for rural satellite offices of providers.

Rationale:

Oncologists in rural areas provide chemotherapy to beneficiaries through satellite offices. If they can receive chemotherapy drugs in their main office, they will have the option of participating in the CAP program.

Implications:

Spending. Negligible.

Beneficiary and provider. This would allow rural providers to participate in the CAP program. It could help preserve access for beneficiaries in rural areas.

The CAP replacement model

Some potential vendors have suggested an alternative model to the CAP program, called the replacement model. Under this model, physicians would estimate the type and quantity of drugs they required for all of 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. Physicians would not have to write separate prescriptions for each patient and would not have to separate inventory by patient (although they still would need to keep drugs for Medicare beneficiaries separate from drugs for their other patients).

Chemotherapy and quality of care

The Congress directed the Commission to report whether quality of care was affected by Medicare payment changes for chemotherapy services. Not surprisingly, clinicians we interviewed think the quality of services they provide is quite high, and patients are generally satisfied with the quality of care they receive. We found no indication that quality of care has been affected by the payment changes. However, few consensus quality indicators for chemotherapy-related services exist, and data to evaluate indicators that do exist are limited. CMS initiated a one-year demonstration project in 2005 to measure the side effects of chemotherapy on patients' quality of life. Current public and private initiatives to define and measure quality of cancer care can provide the framework for a pay-for-performance oncology quality initiative.

We discussed perceptions of differences in quality of care with physicians and patients in the course of our site visits and focus groups. We found that physicians' evaluation of differences in quality of care across settings was subjective and seemed to be dictated by where they practiced. Oncologists in single-specialty practices felt they had more experience in educating patients about their condition and were more likely to hire oncology-certified nurses. They felt they provided more continuity of care and greater convenience for patients. By contrast, physicians practicing in hospital settings pointed to the availability of staff pharmacists to mix drugs, maintaining that this resulted in higher quality and fewer medication errors. They also pointed to greater use of safety guidelines and standard treatment protocols as indicators of higher-quality care.

Beneficiaries who participated in our focus groups received treatment in a variety of settings, including single-specialty oncology offices, outpatient departments of community hospitals, outpatient departments in university hospital cancer centers, and infusion centers of integrated health plans. Almost without exception, beneficiaries praised the quality of care they received.[15] None experienced changes in the quality of care received in the past year. Two focus group participants shifted site of chemotherapy administration from physician offices to HOPDs in 2005. Neither felt quality of care suffered, although both felt there was less coordination of care and greater out-of-pocket expense in the hospital.

Measuring quality of care

It is difficult to measure the quality of care for Medicare patients with cancer. Cancer patients receive care from a variety of specialty physicians, including surgeons, radiologists, radiation oncologists, and medical oncologists. No single physician may be responsible for coordinating care. Typically, patients do not see a medical oncologist until after their cancer has been diagnosed. The patient might not be referred to an oncologist until surgery is completed. In addition, there are many varieties of cancer, each requiring its own treatment protocols and drug regimens. Physicians may find that treatment advances make last year's best practice obsolete. Many existing quality measures are related to screening guidelines, more relevant for primary care physicians and health plans than for medical oncologists. Others apply to a specific type of cancer and not to the patient population of all medical oncologists.

CMS quality-of-life demonstration project

CMS initiated a one-year demonstration project designed to evaluate the severity of side effects experienced by chemotherapy patients. This was also a way to provide additional funds to oncologists. The project attempts to measure how chemotherapy affects the level of fatigue, nausea, and pain experienced by patients. In 2005, all oncologists were eligible to receive $130 per patient per day for asking chemotherapy patients three questions about how they had responded to treatment. Payment includes a 20 percent copayment by beneficiaries. Answers are coded on a 4-point scale.

The Commission and others (OIG 2005) have serious concerns about the validity and methodology of this project:

- It does not control for type of cancer, disease stage, or patient performance status. Performance status refers to how the cancer affects the daily living abilities of the patient.[16]
- It was announced and implemented without any period for comments by clinicians and researchers.
- There is no uniform data collection process. In some practices we visited, nurses were asking patients the three questions and coding the results based on their interpretation of the patients' answers. In other practices, patients were given a questionnaire and provided their own coded responses.
- In some cases, patients reported symptoms within the past week. In other cases, they reported on the basis of their condition at the time of the survey.
- No data are collected on what interventions were initiated to alleviate reported symptoms.

While all practices we visited were participating in this project, most oncologists did not believe it would lead to quality improvements for patients or produce any useful research findings. Many expressed concern that patients were charged copayments as part of the billing process.

CMS recently announced that the demonstration project will be continued in an altered form in 2006. The agency lowered payments to $23 and changed data requirements to provide information on patient care. The goal of the demonstration is to collect data on what physicians do for patients with different cancers at different disease stages. Physicians will use new codes to report on the purpose of the patient visit, the stage of the patient's cancer, and whether the physician used clinical guidelines in the treatment of the patient. Physicians will describe the purpose of the visit, such as evaluation, supervising therapy, monitoring the disease, and end-of-life care. For each visit, the physician will note whether or not they were following clinical guidelines. The physician can explain reasons for not following guidelines. For example, the physician might note that no guidelines exist, or the guidelines are not appropriate in the case of a particular patient. Physicians will be eligible to receive the demonstration payments in connection with higher level oncology evaluation and management visits by cancer patients. Only hematologists and medical oncologists are eligible to participate in the demonstration.

The CMS 2005 project did demonstrate that practices can collect and report quality data on claims in a timely manner without undue burden. Despite general agreement that the project was flawed, oncologists and public and private partners have initiated a variety of other initiatives to design and collect data that can be used to monitor and improve quality of care for chemotherapy patients. As these indicators are validated, they could form the basis of a pay-for-performance program for oncology.

Oncology quality initiatives

The Institute of Medicine (IOM) report, *Crossing the Quality Chasm* (2001), outlined a framework for improving the nation's health care quality and called on all payers to align payment policies to encourage and support quality improvement. The IOM identified six goals for a quality health care system: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. Physicians and researchers in a number of settings were encouraged by the report to continue ongoing efforts to measure and improve the quality of cancer care. The National Quality Forum (NQF) has implemented a cancer care quality measures project in collaboration with federal health agencies. The American Society of Clinical Oncology (ASCO) has developed a practice-based quality improvement initiative. The Community Oncology Alliance (COA) also has proposed pilot projects to improve measurement of quality of care.

Quality of cancer care measures project

With funding from the National Cancer Institute, the Centers for Disease Control, CMS, and the Agency for Healthcare Research and Quality, NQF established the quality of cancer care measures project. NQF has brought together panels of experts to develop and review consensus standards for measuring quality cancer care. The technical panels are addressing measure sets for treatment of breast cancer, colorectal cancer, and symptom management/end-of-life cancer care. The steering committee has made recommendations for breast cancer consensus standards but has not yet addressed measure sets for colorectal cancer or symptom management.

QOPI initiative

ASCO is sponsoring an ongoing, practice-based system of quality measurement called the Quality Oncology Practice Initiative (QOPI). Participating oncologists developed a set of quality measures based on clinical guidelines and consensus-supported indicators of quality care. Most measures are designed to be applicable for different types and stages of cancer although some relate to end-of-life care and several are specific to breast or colorectal cancer. For example, some measures relate to use of specific drug regimens for patients with breast cancer. The initial pilot project was tested on seven oncology groups located in seven states. Participation is voluntary. Twice yearly, practices report de-identified data from patient charts chosen retrospectively on the basis of a specified chart selection formula. Each practice reviewed medical records from the 25 most recent patients with invasive malignancies. Depending upon patient case mix, an additional 10 to 20 medical records were reviewed for patients with diagnoses of lymphoma, breast cancer, or colorectal cancer. Practices also reviewed records of 10 patients who had died of cancer. Each

Table 4

Selected quality indicators from QOPI study

Indicator	Range in scores among groups (percent)
Was pain addressed?	30–90%
Was G-CSF given per guideline?	0–88
Were serotonin antagonist antiemetics given per guideline?	83–100
Were corticosteroids added per guideline?	60–97
Were erythroid growth factors given per guideline?	37–100
Was a pathology report available?	94–97
Was staging completed?	78–93
Were flow sheets used when chemotherapy was given?	None*
Was a signed consent for chemotherapy in the chart?	2–100

Note: QOPI (Quality Oncology Practice Initiative), G–CSF (granulocytic growth factor). A perfect score is 100.
*Indicates all groups used flow sheets.

Source: Neuss 2005.

practice reviewed up to 85 medical records. Data are reported on a secure website developed for this purpose. In a published study on the results of the pilot project, researchers (Neuss et al. 2005) found statistically significant differences among the groups for a majority of the measures (Table 4). For example, there was wide variation in the extent to which practices addressed patient pain. Because of the small size of the original sample, we cannot use these data to draw conclusions about care provided by oncologists nationwide. However, the project is ongoing, with an increasing number of practices participating.

The National Committee for Quality Assurance (NCQA) is in preliminary talks with ASCO to conduct an independent assessment of cancer care quality based on the QOPI tool. The process for the development of performance thresholds and the mechanisms for data collection and transfer are undetermined. Physician practices who meet performance standards could get NCQA recognition as quality providers.

Four QOPI measures concern the use of ancillary drugs for chemotherapy patients. These drugs treat the side effects of chemotherapy, and their appropriate use is a crosscutting quality measure. Practices' use of serotonin antagonist antiemetics for treatment of nausea according to guidelines was quite high. Practices exhibited more variation in the appropriate use of other drugs. For example, practice use of granulocyte colony stimulating factor for neutropenia according to clinical guidelines ranged from 0 to 88 percent. Use of erythroid growth factors for anemia according to clinical guidelines varied from 37 to 100 percent overall, but average compliance with guidelines declined from 72 percent in round 1 to 60 percent in round 2. Although the sample size is very small, practice variation on these indicators suggests that CMS collection of

data on the use of ancillary drugs according to clinical guidelines could lead to improved quality of care.

Community Oncology Alliance pilot projects

COA has established a committee, the Quality, Safety, and P4P (QSP) Committee, to solicit recommendations from community oncologists, oncology nurses, and practice administrators on improving the documentation, safety, and quality of cancer care. QSP has recommended ways to improve the utility of the CMS quality-of-life demonstration including providing patient performance status information on claims. It has also suggested that CMS develop a pilot project in which oncology practices could develop and validate measures to collect staging information in a standard fashion. Currently, oncologists stage patients at diagnosis, determining how far the cancer has progressed. Oncologists use the staging to determine appropriate therapy. This initial stage continues to define the patient's cancer, even if the disease progresses and alternative treatments are initiated. QSP suggests that a pilot project could be used to develop and validate standardized measures for staging that reflect changes in patient condition over time. This measure then could be used to provide more comparable data on symptom management and treatment regimens.

In our March 2005 Report to Congress, the Commission (MedPAC 2005b) described the requirements necessary before pay-for-performance programs can be implemented to distinguish among health care providers.

- Consensus must exist on a core set of quality measures;
- Where necessary, adequate risk adjustment must be available;
- Data used to measure quality must be collectable without undue burden on providers or the program;
- There is room for improvement on the dimensions of quality we can measure.

In the case of chemotherapy, crosscutting measures that apply to a variety of different cancers also would be preferable.

Oncologists and both public and private institutions are undertaking a variety of initiatives to develop and implement measures that meet these criteria. The Commission supports these efforts.

RECOMMENDATION 2

The Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments.

Rationale:

Medicare demonstration projects are designed to test innovative strategies for improving delivery and quality of care for beneficiaries without increasing program spending. To test innovations, CMS must design projects according to accepted research standards. Those standards include a strategy for evaluation. Most researchers do not believe that the quality-of-life demonstration program can be evaluated, and it is hard to see how the data generated can provide useful research findings.

Moreover, the Commission's and the Congress' ability to assess the impact of changes in payments for oncology drugs and drug administration services has been compromised by the two oncology demonstration projects. These projects are not budget neutral. They are designed to increase payments to specific specialties. In general, the Commission finds that if payment rates are not accurate, CMS and the Congress should address the issue with Medicare payment policies. It should not make payment policy through the creation of demonstration projects.

Implications:

Spending. This recommendation should have no effect on program spending.

Beneficiary and provider. Focusing the program's resources on projects designed to improve care delivery and quality should benefit beneficiaries and providers over the long run.

Use of erythroid growth factors

In one case, use of erythroid growth factors according to clinical guidelines, CMS can begin collecting data and using them as part of a pay-for-performance initiative immediately. Erythropoeitin alpha and darbepoeitin alpha are used for the treatment of anemia following chemotherapy as well as some other indications. Medicare expenditures for erythroid growth factors account for the highest percentage of Medicare Part B drug spending. In 2001, non-end-stage renal disease (ESRD) erythropoietin accounted for over 12 percent of Part B drug spending (MedPAC 2003). Since a competing product, darbepoeitin alpha entered the market in 2002, combined spending for the two products has risen rapidly. Expenditures by oncologists increased 33 percent from 2001 to 2002 and 51 percent from 2002 to 2003. In addition, Medicare expenditures by internists for darbepoeitin alpha are the highest for any Part B drug.

At the same time, concerns have been raised about drug safety and potential under- and overuse of these products. As noted above, ASCO's QOPI project found wide variation in use of these growth factors according to clinical guidelines. In 2004, the Food and Drug Administration (FDA)(Steensma and Loprinzi 2005, Rizzo et al. 2002) responded to safety concerns about the use of these products 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. It also issued recommendations about the target rate of hemoglobin increase.

Some local carriers have attempted to limit the use of erythroid growth factors in accordance with FDA regulations and clinical guidelines. Although several carriers have issued local coverage decisions defining appropriate use of these products, carriers are hampered by their lack of access to all relevant clinical data. 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 the medical record. Hemoglobin level is variable. If the hemoglobin level is recorded on each claim, Medicare will be able to track whether the hemoglobin level 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. Medicare could require that all providers who submit claims for erythroid growth factors also provide hemoglobin levels on the claim form.

RECOMMENDATION 3

The Secretary should require providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

Rationale:

Measuring appropriate use of erythroid growth factors meets many of the Commission criteria for quality measures. Clinical guidelines exist. Use of growth factors is crosscutting, appropriate for many, although not all, types of cancer. Practices can provide hemoglobin levels on Medicare claims with minimum additional burden. CMS would not have to risk-adjust results. The initial QOPI study showed variation in use of the product and suggested room for improvement.

Implications:

Spending. This recommendation should have no effect on program spending. It could reduce program spending if the data show that erythroid growth factor is being overused.

Beneficiary and provider. This recommendation could increase the quality of care for Medicare beneficiaries. It would create minimal additional provider burden. Researchers would have more data available to measure the effect of the medication on quality of life and survival of cancer patients.

Conclusion

In the past couple of years, physician practices have been affected by new technologies and new treatment guidelines. These changes are likely to affect Medicare spending for chemotherapy and related services.

- New chemotherapy agents developed through biotechnology have been approved by the FDA. Manufacturers charge increasingly high prices for new drugs like Avastin and Erbitux. For example, one practice reported that a round of treatment with Avastin costs about $12,000 every two weeks. Patients continue to receive this treatment until their condition worsens. An increasing number of patients may have difficulty paying their coinsurance. This means that beneficiaries may not receive the most effective treatment for their condition or that physicians may not collect the full Medicare payment for some patients.

  In addition, physicians sometimes face uncertainty about whether these therapies will be covered by insurers, including Medicare, for a particular type of cancer. This uncertainty may affect treatment choice and site of care.

- PET scans have been found useful in helping physicians determine the stage of particular cancers and develop treatment plans. CMS has issued national coverage decisions approving the use of this technology for a number of different cancers. Some practices are purchasing this technology for use in their offices. The Commission is looking at ways to address the appropriateness of Medicare payments for imaging services.

- Clinical research has suggested improved patient outcomes when chemotherapy is used along with other forms of treatment. For example, chemotherapy may be used before or after surgery. As a result, the number of patients receiving chemotherapy and the duration of the treatment they receive is likely to continue increasing.

In general, the high cost of new chemotherapy agents, the increasing number of Medicare beneficiaries receiving chemotherapy, and the development of new treatment patterns that lead to the use of more drugs and more rounds of chemotherapy for individual patients are likely to result in a continuing increase in Medicare payments for Part B drugs and drug administration services. The Commission will continue to monitor access and quality of chemotherapy services provided to Medicare beneficiaries.

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Endnotes

1. The MMA also changed the way Medicare pays for outpatient drugs under the hospital outpatient department PPS, but those changes are outside the scope of this report.

2. ASP represents the weighted average of prices charged for a product in the United States. It is based on data submitted quarterly by pharmaceutical manufacturers and is net of rebates and discounts offered to purchasers by the manufacturers. Some prices are excluded from calculation of ASP, including prices paid by the Department of Veterans Affairs and other federal purchasers.

3. E&M visits must be coded level 2 or above.

4. Throughout this report the terms oncology and medical oncology are defined as the specialties of hematology, hematology/oncology, and medical oncology. The specialty of radiation oncology is not included.

5. CMS provided the Commission with all carrier-paid claims for a list of chemotherapy-related codes supplied by the Commission. The claims cover somewhat less than half of 2005 and include only those claims submitted and scheduled to be paid through June 22, 2005. To develop a comparable 2004 file, we used the same set of date cutoffs on the 2004 5 percent standard analytic file data. That is, we took claims incurred and paid through June 22, 2004. For both files, only claims lines allowed for payment (not denied) were included in the analysis.

   Variation in claims processing times between years should have a negligible effect on the totals. Carrier-processed claims are typically paid rapidly. For the chemotherapy administration and drug codes in question, the median lag between date of service and scheduled date of payment was 13 days for the 2004 claims sample and 15 days for the 2005 data. This suggests that the claims "tail" (services incurred in the period but not paid in time for inclusion in the analysis) was relatively small, and that we may slightly understate actual 2005 volume (relative to 2004), due to the slightly slower claims processing in 2005. The net result is that we are estimating the change in use from two (presumed) identical part-year files, both of which contain claims for roughly 40 to 45 percent of the full-year data.

6. For our claims analysis, chemotherapy drugs are defined as those drugs included in the CMS Berenson-Eggers Type of Service (BETOS) category of chemotherapy drugs. Some drugs not included in this category are also used for the treatment of cancer.

7. Using a slightly different cutoff date and different growth assumptions, OIG (2005) estimated that spending for the demonstration project would equal $270 million in 2005.

8. Hospitals in these markets also reported they were treating increasing numbers of patients with supplemental insurance who required expensive new drugs.

9. Some prices, including those paid by federal purchasers, are excluded from the calculations.

10. Denileukin diftitox is used to treat a form of lymphoma, a rare type of cancer that affects certain white blood cells and causes lesions to develop on the skin.

11. Our contract with the vendor does not allow us to present prices for specific drugs.

12. For this analysis we focused on prices paid by clinics and hospitals.

13. The range is calculated as the difference between the price at the 75th quartile and the 25th quartile.

14. In the interim final rule, CMS noted that participating CAP physicians could maintain an electronic or paper inventory rather than separate inventories for each patient. The agency also stated that when a CAP drug was not administered in the specified time frame, the participating physician must contact the CAP vendor to discuss what to do. If the drug was unopened and it was permissible under state law, the physician could retain the drug for administration to another Medicare beneficiary at a later date.

15. The one exception was a beneficiary dually eligible for Medicare and Medicaid who received treatment in the HOPD of a safety-net institution.

16. The Eastern Cooperative Oncology Group has developed a 6-point scale to measure performance status. This scale has been validated and is frequently used as a component of data collected in clinical trials.

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 oncologist; 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

Methodology: Price and quantity of drugs

Methodology: Price and quantity of drugs

Price and quantity (or volume) indices provide an aggregate measure of the average changes in price and quantity (Table B-1). The price index compares the cost of a fixed "basket" of drugs in different years. The difference in the total cost of that basket of drugs, evaluated at the two price levels, is the measure of price change. Similarly, the quantity index asks how much the 2004 and 2005 "baskets" of drugs would have cost if they had both used prices from a single year. The difference in the cost of the baskets, holding prices constant, is the measure of the change in the quantity of drugs. If the basket of drugs remained the same, the difference would represent the number of units of drugs provided. However, if the basket of drugs changed, the measure of quantity would include the change in drug mix. Thus, if cheaper drugs are replaced by more expensive drugs, the change will be counted as an increase in the quantity or volume of drugs provided. Using this methodology, we consider the substitution of an expensive drug for a cheaper one as an increase in the *quantity* of drugs, not the *price* of drugs.

To determine the overall effect of pricing changes from 2004 to 2005, we estimated what Medicare would have paid if drugs billed in 2004 were paid for according to the Medicare payment rates (average sales price (ASP) + 6%) as of October 2005. Prices for 2004 were estimated using average allowed charge per unit as calculated from the claims. Prices for 2005 were based on Medicare payment rates for October 2005. Drugs were classified using Berenson-Eggers Type of Service (BETOS) categories to include chemotherapy drugs, erythroid growth factor, and other carrier-billed drugs. Using this methodology, we calculated that the same basket of chemotherapy drugs purchased in 2004 would cost 31 percent less in 2005. Chemotherapy drugs and erythroid growth factor together would cost 28 percent less in 2005. The entire market basket of carrier-billed drugs in 2004 would cost 22 percent less in 2005. These figures reflect changes in prices but do not account for changes in drug mix or the volume of drugs purchased.

Table B–1

Change in price and quantity indices for chemotherapy agents, 2004–2005

Type of change	Percentage change
Quantity change, holding prices constant at:	
2004 levels	30%
2005 levels	20
Price change, holding quantities constant at:	
2004 levels	–28
2005 levels	–34

Source: Direct Research analysis of partial year, Medicare physicians/supplier claims files, 2004–2005.

Table B–2

Number of claims lines for chemotherapy drugs, 2004–2005

	Number of lines		
Cost per claim line	**2004**	**2005**	**Percentage change**
$1000 and higher	287,920	340,914	18%
$500–$1000	579,480	564,929	–3
$100–$500	358,240	347,166	–3
$100 and lower	896,200	787,747	–12
Total	**2,121,840**	**2,040,756**	**–4**

Note: A claim line represents the Medicare payment rate for a drug unit multiplied by the number of units administered to a patient on a given day.

Source: Direct Research analysis of partial year, Medicare physicians/supplier claims files, 2004–2005.

This is an important consideration because the mix of chemotherapy agents shifted strongly toward higher-cost-per-dose agents in 2005. In Table B-2, we use the average cost per claim line as the estimate of the cost per dose. In other words, the claim line represents the Medicare payment rate for a drug, multiplied by the number of units of that drug provided in a particular chemotherapy session. One claim line may equal many units of an inexpensive drug or a smaller number of units of an expensive medication. Agents with average 2005 costs over $1,000 saw an 18 percent increase in the number of times they were billed. Agents costing under $100 per line saw a 12 percent decline in the number of claim lines billed. Overall, the number of claim lines for chemotherapy agents declined 4 percent between the years. This finding suggests that physicians may be using fewer combination therapies in a single session. (This appears to be part of an ongoing trend. The number of claims lines for chemotherapy agents declined 3 percent from 2003 to 2004.)

APPENDIX C

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 1

The Secretary should allow an exception to the competitive acquisition program (CAP) delivery rules for rural satellite offices of providers.

Yes: *Bertko, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Hansen, Kane, Milstein, Muller, Nelson, Reischauer, Scanlon, Smith, Stowers, Wolter*
Absent: *Burke*

Recommendation 2

The Secretary should use his demonstration authority to test innovations in the delivery and quality of health care. Demonstrations should not be used as a mechanism to increase payments.

Yes: *Bertko, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Hansen, Kane, Milstein, Muller, Nelson, Reischauer, Scanlon, Smith, Stowers, Wolter*
Absent: *Burke*

Recommendation 3

The Secretary should require providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

Yes: *Bertko, Crosson, DeBusk, DeParle, Durenberger, Hackbarth, Hansen, Kane, Milstein, Muller, Nelson, Reischauer, Scanlon, Smith, Stowers, Wolter*
Absent: *Burke*

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