CHAPTER 4

Payment for dialysis

RECOMMENDATIONS

4A The Congress should direct the Secretary to:

- eliminate differences in paying for composite rate services between hospital-based and freestanding dialysis facilities; and
- combine the base composite rate and the add-on adjustment.

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

4B The Secretary should:

- eliminate differences in paying for injectable drugs between hospital-based and freestanding dialysis facilities; and
- use average sales price data to base payment for all injectable dialysis drugs that are separately billable in 2006.

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

4C The Congress should give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare it with average sales price data. The Secretary should collect data on the acquisition cost and payment per unit for drugs—other than erythropoietin—that hospital-based providers furnish.

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

CHAPTER 4

Payment for dialysis

In this chapter

- Improving the current payment system
- Modernizing the outpatient dialysis payment system

Through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Congress improved payment for dialysis services—for example, by adding a case-mix adjuster to the payment system. But Medicare continues to pay dialysis providers differently based on site of care and type of drug. MedPAC recommends a series of changes to improve current payment policies. The Congress should eliminate differences in paying for composite rate services between freestanding and hospital-based facilities and should combine the composite rate and the add-on adjustment. The Secretary should use the same payment method—average sales price (ASP)—to pay for all dialysis drugs provided by both facility types. The Congress should require that the Secretary implement these recommendations so that aggregate payments in 2006 are equal to what payments would have been under pre-MMA policies. The Secretary should also collect acquisition cost data from dialysis providers to determine whether ASP represents the purchase price that providers incur. However, rationalizing payment for composite rate services and dialysis injectables serves only as an interim solution; broadening the payment bundle would modernize this payment system.

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. This illness occurs at the last stage of progressive impairment of kidney function and is a consequence of a number of conditions, including diabetes, hypertension, glomerulonephritis, and cystic kidney disease. Most individuals with ESRD undergo chronic dialysis treatment to stay alive. The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD. In 2003, the Medicare program covered about 300,000 patients, representing nearly 93 percent of all dialysis patients in the United States.[1]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and regulations that CMS issued to implement the new law substantially changed the outpatient dialysis payment system by:

- paying acquisition cost for most (but not all) separately billable injectable drugs;
- shifting some of the profits previously associated with payments for separately billable drugs through an add-on payment to the prospective payment rate for outpatient dialysis services (the composite rate); and
- adjusting the composite rate for differences in case mix.[2]

However, the MMA does not change the basic structure of the dialysis payment system—separate payment for dialysis treatments and injectable drugs. Providers will continue to receive the composite rate for each dialysis treatment provided in dialysis facilities (in-center) or in patients' homes.[3] In 2005, the base composite rate for hospital-based facilities is $132—on average, $4 more than for freestanding facilities. This difference stems from the Omnibus Budget Reconciliation Act of 1981, by which the Congress mandated separate rates for the two types of facilities.

The Commission has considered whether current payment policies achieve MedPAC's payment policy objectives, which include providing cost-effective, quality care to patients using the most suitable modality in the most suitable setting; promoting access to services; and giving dialysis providers incentives to control costs. This chapter explores these issues in two sections.

The first section discusses how Medicare pays for outpatient dialysis services. We find that the MMA has improved payment for dialysis in some respects—for example, by adding a case-mix adjustment to the payment system. But the MMA continues to pay freestanding and hospital-based facilities differently for providing the same services. This payment method is not consistent with MedPAC's principle of paying the costs incurred by efficient providers who furnish appropriate care, regardless of the care setting. In addition, the new law makes the payment system more complex by creating an add-on adjustment to the composite rate. Consequently, MedPAC's recommendations advise the Congress and the Secretary to:

- pay the same amount for composite rate services and injectable drugs furnished by freestanding and hospital-based providers, and
- simplify the composite rate by combining the base rate and the add-on adjustment.

In the second section of this chapter, we review MedPAC's past recommendations that the Congress (a) broaden the dialysis payment bundle to include commonly furnished services that are not currently in the bundle and (b) account for factors that affect providers' costs, including dialysis method, dose, and patient case mix. We also discuss potential issues that the Commission may explore in the future.

Finally, MedPAC has concluded that an annual review of rates—for the current payment system and one in which the Congress establishes a larger bundle—is essential for dialysis, especially given the current low margins (MedPAC 2005). The Congress and the Secretary should not assume, as they did in the 1990s, that regular rate increases are not necessary because of large margins.

Improving the current payment system

MedPAC recommends that the Congress and the Secretary equalize the composite rate for hospital-based and freestanding providers, combine the composite rate with the add-on adjustment, use the same methodology to pay for all drugs regardless of setting or type, and periodically check the data on drug payment rates. The following two principles underlie these recommendations:

- Medicare should pay the same rate for the same services across different settings;

- Payment should reflect the costs of efficient providers and should be adjusted to reflect the effects on costs of factors that are beyond providers' control.

The intent of these changes is to rationalize the system in the interim, but a better system would combine payment for composite rate services and drugs into a broader bundle.

Paying for composite rate services

The new law does not change Medicare's policy of paying hospital-based facilities $4 more, on average, for composite rate services than it pays freestanding facilities. This difference began with the Omnibus Budget Reconciliation Act of 1981, which mandated separate rates for the two types of facilities. In the 1983 rule implementing the composite rate, the Secretary attributed this $4 difference to overhead, not to patient complexity or case mix.

Some stakeholders have raised concerns that hospital-based providers employ more nurses to deliver care and, consequently, should receive a higher level of payment. MedPAC analyzed staffing levels using 2003 cost report data submitted by freestanding and hospital-based providers. We also analyzed dialysis quality using CMS's Dialysis Compare database. This online database contains information, by facility, on the proportion of patients in 2002 who received adequate dialysis (i.e., having a urea reduction ratio greater than or equal to 65 percent) and the proportion of patients who had their anemia under control (i.e., having a hematocrit greater than or equal to 33 percent).

MedPAC's analysis of these two data sources did find that hospitals reported higher labor costs and employed more nurses, but quality did not differ between the two types of facilities. MedPAC concludes that Medicare should reward facilities based on quality—rather than pay a higher rate simply because the facilities employ more nurses, which *may* lead to better quality. Pay-for-performance programs hold providers more accountable by rewarding those providers who furnish high-quality care and who improve the care that they furnish.

As Table 4-1 shows, hospitals rely more heavily on registered nurses—who are more highly educated and paid—than on dialysis technicians. The opposite is true for freestanding facilities. Hospital-based providers are also less productive than freestanding providers in terms of (a) the total treatments per patient-care staff and (b) in-center hemodialysis treatments per station. This productivity difference relates more closely to the volume of dialysis treatments that a facility provides rather than the facility's location. Analysis of CMS's facility survey shows that hospital-based facilities provided about 20 percent fewer annual dialysis treatments than freestanding facilities (7,800 versus 9,800 treatments, respectively). MedPAC found about the same percentage difference when comparing the number of annual dialysis treatments provided by hospital and freestanding providers in rural areas (5,300 versus 6,600 treatments, respectively) and in urban areas (9,100 versus 11,100 treatments, respectively).

TABLE 4-1

Staffing and productivity vary between freestanding and hospital-based providers

	Freestanding providers	Hospital-based providers
Technicians as a percentage of patient-care staff	49%	30%
Registered nurses as a percentage of patient-care staff	31	50
Total treatments per patient-care staff	711	461
In-center hemodialysis treatments per station	587	522

Note: Patient-care staff comprises registered nurses, licensed practical nurses, nurses' aides, dialysis technicians, dieticians, and social workers.

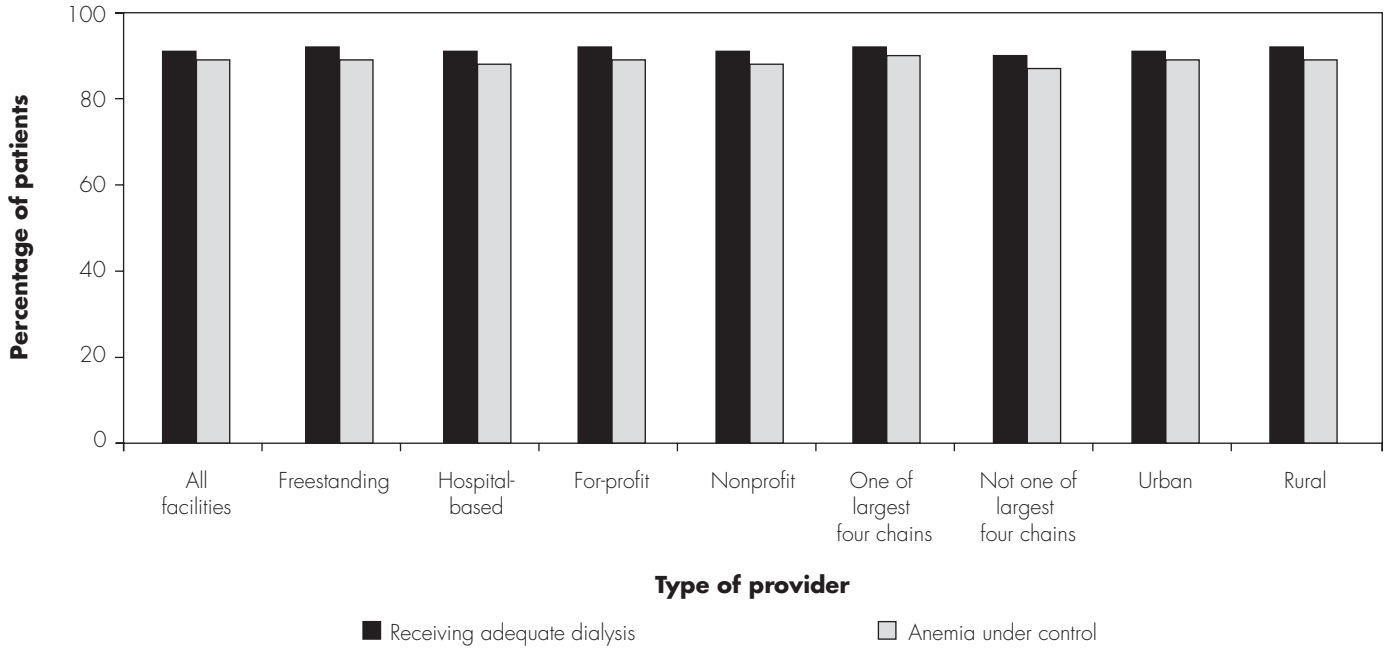
Source: MedPAC analysis of cost reports submitted by freestanding and hospital-based dialysis providers in 2003.

MedPAC's analysis of dialysis quality shows little difference in the proportion of patients who are receiving adequate dialysis and are not anemic (Figure 4-1, p. 90). For both provider types, about 91 percent of all patients received adequate dialysis and about 89 percent of all patients had their anemia under control.

Figure 4-1 also shows few differences in the levels of quality achieved by for-profit versus nonprofit providers; by facilities that are affiliated with one of the four largest chains versus those that are not; and by urban versus rural providers. For each provider type, the proportion of patients who received adequate dialysis is more than 90 percent, and the proportion of patients who had their anemia under control is more than 87 percent.

FIGURE 4-1

Dialysis adequacy and anemia status did not differ among providers in 2002



Note: A total of 3,791 facilities reported information about dialysis adequacy, and 3,831 facilities reported information about anemia status.

Source: MedPAC analysis of data from CMS's Dialysis Compare database.

Many investigators have reported differing results about whether dialysis quality varies based on facilities' ownership and profit status. Previous work by MedPAC showed no association between freestanding facilities' quality of care and their profit status (MedPAC 2003). CMS investigators found no association between profit status and quality measures (that is, adequacy of dialysis, anemia, and nutritional status) (Frankenfield et al. 2000). Port and colleagues (2001) concluded that the risk of mortality does not differ based on facilities' profit status. By contrast, Garg and colleagues (1999) reported higher mortality rates and lower rates of wait-list placement for a kidney transplant for patients who received care at freestanding for-profit facilities than for those who received care at freestanding nonprofit and hospital-based facilities. Other researchers also have found a correlation between facilities' profit status and rates of mortality and transplantation (Devereaux et al. 2002, Ebben et al. 2000, McClellan et al. 1998).

In addition to the different rate that Medicare pays to freestanding and hospital-based providers, the MMA increases the payment system's complexity by creating the add-on adjustment for injectable drugs. The Congress required that the Secretary derive the add-on adjustment by moving dollars associated with the profit margin for the following injectable drugs to the composite rate payment:

- erythropoietin and all other separately billable drugs that freestanding facilities provide, which CMS estimates to be $385 million in 2005, and
- erythropoietin that hospital-based facilities provide, which CMS estimates to be $5 million in 2005.

The resulting add-on adjustment to the composite rate is 8.7 percent.

If the Congress's objective of creating the add-on adjustment is to address how providers subsidize relatively low payments for composite rate services with excessive payments for injectable drugs, combining the base

payment rate and the add-on adjustment is the best way to realize this objective.

In addition, we have concerns about the mechanism that the MMA lays out for recalibrating the add-on adjustment. Beginning in 2006, the new law updates the value of the add-on adjustment—which CMS has currently set at $11.17 for freestanding facilities and $11.52 for hospitals—based on the growth in separately billable drug expenditures. CMS has not yet indicated how it will implement this section of the MMA. Linking the value of the add-on adjustment to post-MMA spending for separately billable drugs may give providers incentives for inappropriate use of the drugs. Linking the add-on adjustment to pre-MMA spending also presents problems because previous payment policies provided incentives for the inappropriate use of drugs.

RECOMMENDATION 4A

The Congress should direct the Secretary to:

- **eliminate differences in paying for composite rate services between hospital-based and freestanding dialysis facilities; and**
- **combine the base composite rate and the add-on adjustment.**

RATIONALE 4A

This recommendation aims to implement a uniform payment policy across settings. Doing so will ensure that Medicare pays the same amount for the same services across different settings. Further, by combining the base composite rate and the add-on adjustment, Medicare will simplify the outpatient dialysis payment system.

IMPLICATIONS 4A

MedPAC considers the implication of this recommendation on spending, beneficiaries, and providers together with the implications of recommendation 4B (pp. 94–95).

It is not clear whether the composite rate and add-on adjustment together form the appropriate level of payment for a dialysis treatment. Dialysis care has changed since 1983, but the Secretary has not rebased the composite rate.[4] Similar to other prospective payment bundles, the product has changed: New technologies have replaced older technologies, and the bundle now includes services that were not available in 1983. As we discuss later in this chapter, when broadening the payment bundle the Secretary will need to identify the medications, services, and equipment that will increase the efficiency of patient care and improve patient outcomes.

In addition, for the current payment system and for one in which Medicare establishes a larger bundle, MedPAC has concluded that an annual review of rates is essential for dialysis, especially given the current low margins (MedPAC 2005). The Congress and the Secretary should not assume, as they did in the 1990s, that regular rate increases are not necessary because of high margins.

Paying for dialysis injectable drugs

Under current law, which reflects both the MMA and previous policy, the Secretary pays dialysis providers differently depending on the specific drug and the site of care. All the payment policies we discuss in this sub-section relate to injectable drugs that CMS pays separately from the composite rate. MedPAC recommends rationalizing payment policy by (a) paying for all dialysis drugs using the same methodology (that is, the same method used for other Part B providers) and (b) periodically checking the ASP data to verify its appropriateness.

Before the MMA, payment for injectable drugs also varied depending on the site of care and on the specific drug.[5] The payment methods—a rate for erythropoietin set in the statute and average wholesale price (AWP) for drugs other than erythropoietin—generated excessive profits for these drugs. Through the MMA, the Congress addressed this overpayment issue by requiring a new payment approach.

Payment methods vary by site of care and type of drug

Under current law created by the MMA, Medicare pays three different ways for dialysis drugs.

Paying for the "top 10 drugs" in freestanding facilities For the 10 injectable drugs that make up the highest share (98 percent) of volume, Medicare now pays freestanding providers using a method called average acquisition payment (AAP).[6] To calculate the AAP, CMS used the acquisition costs that the Office of Inspector General (OIG) collected in a 2003 survey of freestanding providers (OIG 2004).[7] CMS derived the 2005 rates for these drugs by updating the 2003 values using the producer price index (PPI).

Paying for other drugs in freestanding facilities For all other injectable drugs, Medicare pays freestanding providers using a different method—ASP. This method uses prices that manufacturers report to CMS every quarter. CMS set the 2005 rates for these drugs at ASP plus 6 percent.

Paying for drugs in hospital-based facilities Unlike freestanding providers, hospitals' payment for most dialysis drugs uses a third approach—reasonable cost—with one exception: erythropoietin, for which Medicare pays the same AAP rate as that of freestanding providers. CMS derives reasonable cost from a hospital's cost report; the agency calculates this payment by reducing hospital-set charges, including overhead, to costs using a cost-to-charge ratio. Researchers do not yet clearly understand the relationship between payment based on reasonable cost and payment based on hospital-incurred acquisition cost.

What is the best way for Medicare to pay dialysis facilities for drugs?

Through the MMA, the Congress intended that the payment rates for dialysis drugs more closely approximate the costs that providers incur. Results from a MedPAC-sponsored survey and the OIG suggest that different types of providers use different approaches to purchase drugs, and this sometimes results in different prices. However, the prices that freestanding and hospital-based facilities pay do not vary much based on an analysis of pricing data that MedPAC obtained from IMS Health.

The three different approaches—ASP, AAP, and reasonable cost—all try to estimate the above costs. Paying reasonable costs is probably the least accurate approach, as it may reflect the facilities' charging and accounting practices. In our discussion below, we contrast the two other methods and find that they attempt to measure the same concept. However, ASP shows several advantages over AAP in that the Secretary already collects ASP data for all drugs and ASP data are more up to date.

How do different providers acquire drugs?

The Commission sponsored a series of interviews with hospital-based and smaller freestanding dialysis providers to understand their purchasing strategies for dialysis injectables. Our objective was to better understand how smaller dialysis providers acquire injectable drugs—including whether they purchase drugs directly or through other agents (such as a parent company or hospital pharmacy) and how they negotiate prices with manufacturers. The text box describes how we constructed the sample and the characteristics of the participating dialysis providers.

We found that the smaller providers try to competitively negotiate to obtain dialysis drugs, but manufacturers generally give direct discounts only to the largest volume facilities—those typically affiliated with chains. Respondents to our survey usually acquire drugs from:

- ***Wholesalers***—the primary source used by smaller non-chain–affiliated freestanding facilities. It is common for facilities to obtain drugs from more than one wholesaler. Facilities that agree to purchase most of their drugs from one wholesaler often receive a better price from that wholesaler. Respondents to our survey reported it was difficult to find a wholesaler for drugs not routinely used.
- ***Group purchasing organizations (GPOs)***—an important source for facilities seeking lower prices that GPOs make available through volume purchases. For a fee, the GPO functions as a buying unit for a group of facilities that can take advantage of discounts that manufacturers might offer to volume purchasers.
- ***Manufacturers***—the primary source for facilities that are members of regional chains that can negotiate volume discounts. Providers that purchase directly from manufacturers avoid fees that wholesalers charge.

Respondents indicated that they attempt to negotiate:

- ***Price***—Respondents reported that they can better negotiate for drugs in which clinical substitutes are available. Of the top 10 dialysis injectables, only one has generic alternatives. However, alternative therapies exist among two classes of drugs—those used to treat bone disease and iron deficiency.
- ***Volume***—Providers that purchase larger volumes of drugs can obtain lower prices through discounts and rebates. However, patient needs and cash flow limit the volume of drugs that providers can inventory at any given time.

By contrast to the smaller providers, we learned that the large national chains generally negotiate directly with manufacturers.

Survey of small freestanding and hospital-based dialysis providers

On behalf of MedPAC, the National Opinion Research Center (NORC) and Georgetown University conducted a series of interviews with a small sample of hospital-based dialysis providers and freestanding providers who were not affiliated with the four largest chains. Beginning in March 2005, our contractors conducted interviews by telephone using a semistructured interview guide. NORC and Georgetown University interviewed respondents—including directors of purchasing, directors of pharmacy, and other facility administrators—about how they negotiate prices and acquire dialysis drugs. To date, our contractors have completed 11 interviews with freestanding providers and 4 interviews with hospital-based providers. ■

How do prices vary by type of facility?

Findings from the OIG's report suggest that the price dialysis facilities pay varies between the largest freestanding providers—that is, those affiliated with one of the four largest dialysis chains—and all other freestanding facilities (OIG 2004). The average acquisition cost for the three leading drugs, in terms of Medicare payments, was 8 to 22 percent lower for the largest providers compared with other freestanding providers in 2003.[8] The largest providers reported drug acquisition costs that were 6 percent lower than the ASP of the top 10 drugs; by contrast, other freestanding facilities reported drug acquisition costs that were 4 percent above the ASP. The OIG based its report on data collected from each of the four largest dialysis providers and a sample of all other freestanding facilities. The OIG did not include hospital-based providers in its report.

To compare the purchasing strategies of freestanding and hospital-based providers, MedPAC obtained data from IMS Health on the national average purchase prices for the top 10 dialysis injectables during the fourth quarter of 2004. This database included the national average purchase prices for "clinics," which include sales to freestanding dialysis providers, and "nonfederal hospitals," which include sales to hospital-based dialysis providers.[9] Because IMS collects data from sales invoices and these sales invoices do not include off-invoice discounts or rebates, the average purchase price overstates the amount that providers actually pay for drugs. In addition, the average purchase price includes purchases by both dialysis and nondialysis providers.

Our analysis suggests that the purchase prices for the top dialysis injectables do not vary substantially between freestanding providers and hospitals. The weighted average purchase price for all of the study drugs was, on average, 4 percent greater for "nonfederal hospitals" compared with "clinics." We calculated the weighted average purchase price by weighting the average purchase price for each drug by its proportion of total Medicare payments.

How do AAP and ASP compare?

Ideally, Medicare should arrive at the same payment rate for a particular dialysis injectable by using either ASP or AAP data. Both data sources aim to determine the purchase price of drugs—that is, the net of all rebates and discounts. CMS derives AAP data from a special survey of dialysis providers. By contrast, CMS collects ASP data from all manufacturers for all drugs, updates ASP data quarterly, and uses this data source to pay for injectables that other Part B providers furnish.[10]

The most important difference between the two methods is the frequency by which CMS will update AAP data to reflect actual transaction prices. AAP data may not accurately reflect providers' acquisition costs in 2006 and beyond if the negotiating process changes the price that manufacturers charge. In 2005, the OIG will determine the prices of new drugs (which did not have a billing code before 2004). Otherwise, the update may include an inflation factor (such as the PPI). In addition, AAP does not provide information on all injectable drugs that dialysis facilities currently use. Finally, AAP does not provide information about the prices that hospitals pay.

TABLE 4-2

AAP and ASP for dialysis injectables vary somewhat in 2005

	AAP 2005	ASP plus 6 percent (1st quarter 2005)	ASP plus 6 percent (2nd quarter 2005)
Erythropoietin	$9.76	$9.32	$9.25
Calcitriol	0.96	0.71	0.86
Doxercalciferol	2.60	2.80	2.78
Iron dextran	10.94	11.06	11.22
Iron sucrose	0.37	0.36	0.37
Levocarnitine	13.63	14.65	11.12
Paricalcitol	4.00	4.02	3.97
Sodium ferric gluconate complex	4.95	4.83	4.73
Alteplase, recombinant	31.74	30.15	30.09
Vancomycin	2.98	2.42	3.19

Note: AAP (average acquisition payment), ASP (average sales price). Average acquisition payment for 2005 reflects the average acquisition cost for 2003 updated by the producer price index.

Source: CMS 2005.

MedPAC compared the payment rate under AAP to the corresponding rate for each of the top 10 dialysis drugs if ASP plus 6 percent were the reference price (that is, the rate used to pay other Part B providers [Table 4-2]). This comparison shows similar rates for some drugs but shows that for others, notably erythropoietin, the ASP rates have been falling over the last quarter.[11] The more recent ASP data will more likely reflect current negotiations between manufacturers and purchasers rather than the AAP rates.

Based on our analysis of how different providers acquire and receive payment for injectable drugs—and of the similarities and differences between ASP and AAP—MedPAC concludes that:

- Medicare's current method of paying for separately billable drugs should not vary between provider types.
- Both ASP and AAP aim to determine the purchase price of drugs (which is the net of all rebates and discounts); thus, CMS should derive a similar price from either data source.
- Similar incentives exist for providers to obtain the best possible purchase price under both ASP and AAP.
- CMS regularly collects ASP data and uses it to pay for other Part B injectables. By contrast, CMS does not regularly collect AAP data and does not use this data source to pay for other Part B injectables.
- CMS updates ASP data regularly to reflect actual transaction prices; thus, ASP data would better reflect the prices paid by dialysis providers over time than would AAP data.

RECOMMENDATION 4B

The Secretary should:

- **eliminate differences in paying for injectable drugs between hospital-based and freestanding dialysis facilities; and**
- **use average sales price data to base payment for all injectable dialysis drugs that are separately billable in 2006.**

RATIONALE 4B

This recommendation would make a uniform payment policy across settings. In contrast to AAP data, ASP data are already collected by the Secretary, are regularly updated by the agency, and include data for all drugs.

IMPLICATIONS 4A AND 4B

Spending

- Through recommendations 4A and 4B, MedPAC intends to maintain overall budget neutrality with pre-MMA spending in 2006.

Beneficiary and provider

- Some facilities could receive higher payments or lower payments. We do not expect this recommendation to affect providers' willingness and ability to provide quality care to Medicare beneficiaries. These recommendations do not substantially change beneficiary cost sharing, nor should they have a negative effect on beneficiary access to quality care.

At what level should Medicare set ASP?

At issue is the level that Medicare should set ASP for dialysis drugs. By setting the initial payment rate at ASP plus 6 percent, the Secretary will account for the variation in the purchase price for dialysis injectables across different types of providers. Our analysis of data from the OIG and IMS—and our survey of smaller providers—suggests that some providers can negotiate larger discounts for drugs than others. Together, these data sources suggest that the four largest freestanding dialysis chains obtain the lowest purchase price for injectable drugs, followed by hospital-based and smaller freestanding providers.

Over the long term, the Secretary should set a payment rate that reflects efficient providers' costs. In the next section, we recommend that the Secretary periodically collect acquisition cost data from a sample of providers and compare it to the ASP data. By periodically collecting data on providers' costs, the Secretary can make adjustments as necessary in the ASP level.

Improving data on paying for drugs

Although the Commission recommends using ASP data to pay for all dialysis drugs, we caution that these data do have some limitations. ASP data may deviate from AAP data because:

- The Secretary derives ASP on pricing data that manufacturers submit for all "channels" (that is, types of purchasers of a particular dialysis drug, not just dialysis providers). Thus, ASP reflects the purchase price of dialysis providers as well as that of other providers, such as physicians, nursing facilities, hospitals, and home health providers. The Secretary's calculation of ASP includes all sales except those that are exempt from Medicaid's best price calculations.

  However, the effect of basing the ASP calculation on nearly all sales may not be large. According to stakeholders, medical professionals use the top 10 dialysis drugs, except for vancomycin, primarily to care for renal patients.

- ASP may, in fact, understate the price that providers pay because ASP does not include wholesalers' service fees.

Because ASP and AAP might deviate over time, MedPAC recommends that the Secretary periodically collect acquisition cost data from both freestanding and hospital-based dialysis providers and compare it to ASP data. In doing so, the Secretary will better understand the effect of including nearly all sales in the calculation of ASP data. By monitoring the comparability of both data sources over time, the Secretary will be able to set the payment rate to reflect efficient dialysis providers' costs.

The Secretary will need additional data to assess the impact of using ASP data for hospitals. Such an assessment is necessary in order to carry out the MMA's intent—that is, to modify the composite rate so that it accounts for any profit associated with the previous payment method and to maintain budget neutrality with pre-MMA payment levels.

To conduct the assessment, the Secretary will need to obtain data to estimate hospitals' costs and Medicare's payment per unit for these drugs. No published source identifies the unit payment for these drugs because Medicare pays hospitals their reasonable costs. We attempted to calculate the unit payment from 2003 claims data, but the accuracy of the data fields we needed to make this calculation was unclear, particularly the number of units furnished and Medicare's payment to the hospital.

As mentioned earlier, the OIG will be conducting a second study on the difference between (a) the Medicare payment amount for separately billable dialysis drugs for which a billing code did not exist prior to January 1, 2004, and (b) the acquisition costs of such drugs. The OIG could also collect hospitals' payment and cost data for the top 10 dialysis injectables (other than erythropoietin). The Secretary also might collect data on hospitals' cost and payment per unit for drugs in the agency's demonstration study of a broader bundle, which will begin in 2006.

RECOMMENDATION 4C

The Congress should give the Secretary the authority to periodically collect average acquisition cost data from dialysis providers and compare it with average sales price data. The Secretary should collect data on the acquisition cost and payment per unit for drugs—other than erythropoietin—that hospital-based providers furnish.

RATIONALE 4C

By collecting data on dialysis providers' acquisition cost, the Secretary will be able to assess that data's comparability, over time, to ASP data.

IMPLICATIONS 4C

Spending

- This recommendation will not increase federal program spending relative to current law.

Beneficiary and provider

- Some facilities could receive higher payments or lower payments. We do not expect this recommendation to affect providers' willingness and ability to provide quality care to Medicare beneficiaries.

Smaller facilities that are not affiliated with a dialysis chain cannot purchase drugs as inexpensively as the largest chain providers. To protect beneficiaries' access to these smaller facilities, policymakers might consider extending to dialysis providers the competitive acquisition program for outpatient drugs and biologicals. Beginning in 2006, the MMA gives physicians the choice of either obtaining certain Part B injectables from contractors (who would then bill Medicare) or continuing to purchase the drugs and receive ASP plus 6 percent from Medicare.

Impact of implementing MedPAC's recommendations

We assessed the impact of implementing our recommendations that refine payment policies for composite rate services and dialysis injectables by modeling 2006 spending under pre-MMA policies and under MedPAC's recommendations (Table 4-3). This analysis also includes our recommendation to update the payment for composite rate services in 2006 (MedPAC 2005). This analysis serves illustrative purposes only. If the Congress and the Secretary adopt MedPAC's recommendations, the Secretary will need to determine

TABLE 4-3

Estimated impact of MedPAC's recommendations to refine outpatient dialysis payment policies, 2006

	Freestanding			Hospital-based			Total		
	Payments in millions			Payments in millions			Payments in millions		
Service	Pre-MMA	Post-MMA	Percent change	Pre-MMA	Post-MMA	Percent change	Pre-MMA	Post-MMA	Percent change
EPO	$2,229	$2,146	–4	$216	$208	–4	$2,445	$2,354	–4
All other drugs	1,022	648	–37	157	157	0	1,179	805	–32
Total: Drugs	3,251	2,794	–14	372	364	–2	3,624	3,158	–13
Composite rate	4,239	4,626		634	670		4,872	5,296	
B–N factor	0	36		0	5		0	41	
Total: Composite rate	4,239	4,662	10	634	675	6	4,872	5,338	10
Drugs and composite rate	**7,490**	**7,456**	**–0.5**	**1,006**	**1,040**	**3**	**8,496**	**8,496**	**0**

Note: MMA (Medicare Prescription Drug, Improvement, and Modernization Act), EPO (erythropoietin), B–N (budget neutrality). The column titled "Post-MMA" reflects MedPAC's recommendations to change payment policies in 2006. MedPAC's recommendations are estimated based on the average sales price plus 6 percent reported by CMS in April 2005 and inflated to 2006 prices. The aggregate composite rate represents the base rate and the add-on adjustment as implemented in CMS's final rule, updated by 2.5 percent, which was MedPAC's most recent recommendation for composite rate services (MedPAC 2005). Spending for aggregate composite rate services includes a budget-neutral factor of $41 million in order for MedPAC's recommendations to maintain budget neutrality with pre-MMA spending levels. See text box for a complete description of the methods. Sums may not total correctly due to rounding.

Source: MedPAC analysis of 2003 claims data submitted by freestanding and hospital-based providers.

Impact analysis of MedPAC's recommendations to refine outpatient dialysis payment

Our impact analysis illustrates payments under pre-Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) policies and payments under MedPAC's recommendations, the latter of which (a) eliminate differences in composite rate and drug payment policies between the two provider types and (b) combine the base composite rate and add-on adjustment. To the extent possible, we used methods similar to those that the Secretary used in the Part B final rule.

As we show in Table 4-3, all spending is expressed in terms of 2006 dollars. For both scenarios, we applied MedPAC's most recent update recommendation (2.5 percent) for composite rate services. For the pre-MMA scenario, we applied the update factor to the base composite rate. For the scenario modeling MedPAC's recommendations, we applied the update factor to the base composite rate and add-on adjustment.

We could not model the impact of changing drug payment policies for injectables other than erythropoietin provided by hospitals. Thus, payment for these drugs remains unchanged when we modeled the impact of our recommendations. Because hospitals receive reasonable cost for these drugs, the Secretary has no data source from which to obtain the per-unit payment for these drugs. By contrast, the Secretary used the Single Drug Pricer for January 2004 to derive freestanding providers' pre-MMA per-unit payment.

MedPAC attempted to derive the payment per unit data from 2003 claims that hospital-based providers submitted. However, after thoroughly reviewing these data, we were unsure of their accuracy because Medicare does not pay according to the number of units reported on the claim. Validating the claims data to data reported on patients' medical records would demand more resources and time than available. Thus, we took a conservative approach: When modeling the effect of our recommendations, we maintained pre-MMA spending levels for these drugs.

To put this omission in perspective, Medicare's payments for drugs other than erythropoietin to hospital-based providers account for a small proportion of total payments for dialysis drugs. In 2003, payments for these drugs accounted for 2 percent of all payments and 5 percent of all drug payments to freestanding and hospital-based providers.

Lastly, our impact analysis does not reflect the case-mix adjustment implemented by CMS on April 1, 2005. Although this adjustment might affect the two types of providers differently, it would not affect overall spending because the MMA mandated that the Secretary implement the case-mix adjustment budget neutral. ■

the impact of these changes on different provider types using the most current data available.

For the pre-MMA payment scenario, we updated the base composite rate by 2.5 percent—MedPAC's most recent update recommendation for composite rate services. To model the effect of our recommendations, we set the payment rate for dialysis injectables at ASP plus 6 percent and updated the aggregate composite rate by 2.5 percent. The text box contains a complete description of the methods.

Through these recommendations, we intend to maintain overall budget neutrality with pre-MMA spending levels. We do so by including a budget neutrality factor with spending for composite rate services. Using the most current data available and updating it to represent 2006 spending and prices, we estimate a budget neutrality factor of about $41 million. Total 2006 spending estimates for composite rate services and for drugs under both scenarios adds to $8.5 billion.

The impact on aggregate spending for composite rate services under MedPAC's recommendations reflects:

- ***The Secretary implementing the single add-on adjustment.*** This action, mandated by the MMA, resulted in transferring dollars from freestanding to hospital-based facilities. The Secretary estimates that

total payments for freestanding facilities decreased by 0.6 percent and payments for hospital-based providers increased by 5.2 percent.

- ***The Congress eliminating the $4 difference between freestanding and hospital-based providers.*** This action, recommended by MedPAC, would result in an estimated aggregate composite rate of $143.58 in 2006. If the Congress does not eliminate the $4 difference, we estimate the aggregate composite rate would be $143.00 and $147.53 for freestanding and hospital-based providers, respectively. Thus, by eliminating the $4 difference, Medicare would increase the composite rate by 0.4 percent for freestanding providers and decrease the rate for hospital-based providers by 2.7 percent. This impact stems from the fact that freestanding providers furnish a much larger share of all dialysis treatments than do hospital-based providers (87 percent versus 13 percent, respectively).
- ***The Congress requiring that the Secretary implement the Commission's recommendations so that aggregate payments in 2006 are equal to what payments would have been under pre-MMA policies.*** In doing so, Medicare would increase the aggregate composite rate by 0.8 percent to $144.70 for both facility types.

Compared with pre-MMA payments, we estimate that aggregate erythropoietin payments will decrease by 3.7 percent for both provider types under MedPAC's recommendations. This decline reflects the difference in the payment rate under pre-MMA policies and the ASP plus 6 percent that MedPAC estimated in 2006.[12]

For freestanding providers, we estimate that aggregate payments under MedPAC's recommendations for all other drugs will decrease by more than one-third compared to pre-MMA levels. This decrease reflects the pre-MMA policy of paying 95 percent of the AWP. We estimate that payments for freestanding providers for all dialysis injectables will decrease by 14 percent.

Because of data limitations, our analysis assumes that hospitals are receiving constant payments for drugs other than erythropoietin. Consequently, we estimate that hospitals' total payments for all drugs will decrease by 2 percent.

Considering spending for both composite rate services and drugs together, we estimate that freestanding providers' payments will decline slightly (by 0.45 percent) and that hospital's payments will increase (by 3.4 percent).

Modernizing the outpatient dialysis payment system

Improving current payment for composite rate services and dialysis injectables serves only as an interim solution; the Congress should also broaden the payment bundle in order to modernize this payment system. Medicare could provide incentives for controlling costs and promoting quality care by broadening the payment bundle to include dialysis injectables and laboratory services that are not separately billable and by linking payment to quality.

Facilities have stronger incentives to control the costs of services included in the payment bundle compared with services that fall outside it—that is, services that are separately billable. Under pre-MMA payment policy, drug spending per patient varied among different provider types, perhaps reflecting providers' differing incentives to furnish drugs under different payment systems. For example, per patient per month spending varied from $453 to $530 for erythropoietin, $69 to $93 for injectable iron, and $67 to $166 for vitamin D analogues across the four major for-profit chains and hospital-based facilities (USRDS 2004). In addition, an earlier MedPAC analysis showed that dialysis quality of care (a) did not significantly differ among facilities with lower and higher costs for composite rate services and (b) was poorer for facilities with higher-than-average costs for composite rate services and for injectable drugs (MedPAC 2003). Differences in case mix may also partly account for these findings. Together, these findings suggest that certain facilities might less efficiently furnish injectable drugs than other facilities, and this inefficiency may in turn reflect less than optimal patient care.

The new law creates incentives for facilities to more appropriately use dialysis injectables, because Medicare pays acquisition cost for most drugs. However, because some providers can negotiate steeper discounts than the acquisition cost and because the payment system pays on a per-unit basis, the new law does not eliminate the incentive for inappropriate use.

Both facility types showed substantial spending for dialysis injectables—$2.8 billion for drugs compared with $4.2 billion for composite rate services in 2003. Spending for drugs accounts for a similar proportion of all dialysis spending for both facility types—39 percent of all spending for hospital-based providers and 41 percent of all spending for freestanding providers in 2003. If the Congress had not implemented the MMA, we estimate that drug spending would have increased to about 44 percent of all spending in 2006.

Spending for laboratory services outside the payment bundle may also be significant. Researchers at the University of Michigan recently estimated that spending for laboratories outside the composite rate was $249 million in 2003. The Government Accountability Office (GAO) previously found that clinically similar ESRD patients received laboratory tests at widely disparate rates. The GAO also concluded that at one extreme, Medicare may be paying for an excessive number of tests; at the other, patients may not be receiving the tests needed to adequately monitor their condition (GAO 1997).

MedPAC has recommended that the Congress should —as soon as possible—refine the outpatient dialysis payment system by broadening the dialysis payment bundle to include commonly furnished services that Medicare currently excludes. The Congress should also account for factors that affect providers' costs, including dialysis method, dose, and patient case mix (MedPAC 2001). MedPAC has also recommended that the Congress implement pay-for-performance for both facilities and physicians who treat dialysis patients (MedPAC 2004). In addition, to promote the delivery of clinically appropriate care, the Secretary needs to continue to develop quality measures and to monitor and improve dialysis care. Together, these recommendations should improve the efficiency of the payment system, better align incentives for providing cost-effective care, and reward providers and physicians for providing high-quality care.

The new law begins to consider expanding the payment bundle. Starting on January 1, 2006, the Secretary must conduct a three-year demonstration of a sample of dialysis providers to test a broader payment bundle.

Future MedPAC issues

MedPAC plans to continue analyzing the following outpatient dialysis payment issues:

- ***Wage index adjustment to the composite rate.*** In the MMA, the Congress gave the Secretary discretionary authority to revise the wage index that the Secretary currently uses in the dialysis payment system. When CMS implemented other changes to dialysis payment required by the MMA, the agency chose not to make changes to the wage index. The agency argued that (a) new statistical area definitions recently published by the Office of Management and Budget will affect payment distribution and (b) the evaluations of the impact of these new statistical areas are necessary before changes to the wage index are made. MedPAC is exploring the implications of more current wage indexes on providers' spending.

- ***Payment for home dialysis.*** One issue for the Congress to consider when modernizing the payment system is whether to maintain the same payment rate for in-center and home dialysis. Currently, the composite rate is the same for in-center hemodialysis and dialysis that is administered in patients' homes—that is, peritoneal dialysis and hemodialysis. In 1981, the Congress mandated that payment not differ in order to encourage patients' use of home dialysis. Historically, providers incurred lower costs for providing home dialysis than in-center dialysis. Despite this cost difference, the use of home dialysis has declined during the past 10 years. Issues that remain to be explored include a comparison of the current use of dialysis injectables by at-home and in-center patients, the impact of the pre-MMA payment system on the use of home dialysis, the impact of pre-ESRD care on the use of home dialysis, and the use of quality incentives to promote home dialysis.

- ***Case-mix adjustment.*** As we mentioned earlier, CMS has recently adjusted the composite rate for age and body mass. Some stakeholders are concerned that this adjustment results in payments that are greater for younger adult patients than for older patients. MedPAC's preliminary analysis confirms CMS's findings. The association between patients' age and providers' cost is "U"-shaped, with pediatric patients, young adults (18 to 44 years of age), and elderly patients (greater than 80 years of age)

incurring higher costs than those of other age groups (patients who are 45 to 59 and 70 to 79 years of age). MedPAC plans to explore factors that may be affecting providers' costs, such as patient compliance and dialysis time. We also plan to evaluate different ways in which the Secretary can case-mix adjust a broader payment bundle.

- ***Part B and Part D coverage for drugs.*** CMS may be considering paying for dialysis injectables under both the Part B and Part D payment systems. MedPAC will be following this issue closely because it can affect beneficiaries' cost sharing under the current payment system of paying separately for dialysis injectables, and because this issue would also complicate the implementation of a broader payment bundle. ■

Endnotes

1 To qualify for the ESRD program, individuals must be insured under the Social Security or Railroad Retirement program, be entitled to monthly benefits under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary.

2 As of April 2005, CMS uses the following measures to adjust the composite rate for differences in case mix:

- age (<18, 18–44, 45–59, 60–69, 70–79, >80 years), and
- two body measurement variables—body surface area and body mass index—calculated from patients' height and weight when they develop ESRD. As of January 2005, CMS requires that dialysis facilities report patients' height and weight on dialysis claims.

CMS does not use the body measurement variables to calculate payments for patients under age 18.

3 In 1981, the Congress mandated that the composite rate include all nursing services, supplies, equipment, and selected drugs associated with a single dialysis session.

4 Although the Secretary has not rebased the composite rate, the Congress updated it twice during the past five years (in 2000 and 2005).

5 Under pre-MMA policies, the payment rate for erythropoietin was the same for freestanding and hospital-based facilities—$10 per 1,000 units. For drugs other than erythropoietin, Medicare paid freestanding facilities 95 percent of the AWP; by contrast, Medicare paid hospital-based facilities reasonable cost for these drugs.

6 The top 10 drugs are erythropoietin, calcitriol, doxercalciferol, iron dextran, iron sucrose, levocarnitine, paricalcitol, sodium ferric gluconate complex, alteplase recombinant, and vancomycin.

7 The OIG is mandated to conduct two studies on the pricing of dialysis drugs. The first study, published in May 2004, examined the pricing of drugs that had a billing code before 2004. The second study, due to the Congress by April 2006, will examine the pricing of drugs that did not have a billing code in 2004.

8 The three leading drugs—in terms of Medicare payments in 2003—for freestanding facilities were erythropoietin ($1.7 billion), paricalcitol ($323 million), and iron sucrose ($153 million).

9 IMS Health collects purchase price data from manufacturers and drug wholesalers.

10 The Secretary derives ASP from sales data that manufacturers submit to the agency no later than 30 days after the close of each quarter. The term manufacturer means any entity engaged in the following activities: (1) production, preparation, propagation, compounding, conversion, or processing of prescription drug products, or (2) packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. The term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. The ASP for a given product is the volume-weighted average of the manufacturers' average sales prices reported to the Secretary across all drugs assigned to a HCPCS code. ASP is the net of all price concessions, including volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates. The Secretary estimates total price concessions using a 12-month rolling price concession. Medicare payment allowances for the first quarter of 2005 are based on submissions from the third quarter of 2004.

11 CMS has not announced any changes to the ASP values for the second quarter of 2005. The agency did revise the ASP values of a few drugs for the first quarter of 2005 to correct technical errors.

12 MedPAC estimated the 2006 average sales price plus 6 percent for erythropoietin by inflating the rate used by CMS in the second quarter of 2005 by an update factor of 4.1 percent. We derived this factor using a combination of historical data on producer prices for prescription drugs and CMS's projections of future growth in nationwide drug spending per person.

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