MEDPAC Medicare Payment Advisory Commission

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June 25, 2007

The Honorable Fortney Pete Stark
Chairman, Subcommittee on Health,
House Ways and Means Committee
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Stark:

Thank you for your inquiry regarding the Commission's findings about the adequacy of Medicare's payments for freestanding dialysis providers and our recommendations on modernizing the outpatient dialysis payment system.

The Medicare Payment Advisory Commission (MedPAC) has a long history in examining issues related to Medicare's payments for outpatient dialysis services. Each year, the Commission assesses the adequacy of Medicare's outpatient dialysis payments and makes recommendations about whether to update the composite rate. In addition, we have also examined and made recommendations on Medicare's method for paying for dialysis services, the quality of dialysis care, and beneficiaries' access to care.

In response to your inquiry, this letter summarizes our past research and recommendations on:

- Trends in the volume of outpatient dialysis services
- Medicare margins for outpatient dialysis services
- Modernizing the outpatient dialysis payment system

## Trends in the volume of outpatient dialysis services

MedPAC has closely monitored changes over time in the volume of composite rate services (i.e., Medicare's prospective payment for each dialysis treatment) and dialysis drugs furnished by freestanding providers (who treat most dialysis patients). One way the Commission tracks utilization trends is by examining Medicare spending for both composite rate services and dialysis drugs. As described in our March 2007 report to the Congress, Medicare's spending for dialysis drugs, including erythropoietin, has grown more rapidly than composite rate services during the past decade (Figure 1 and Figure 2, page 3).

Between 1996 and 2004, the annual growth in payments for composite rate services generally kept pace with the increase in the dialysis population (8 percent versus 6 percent, respectively). The higher growth in composite rate payments between 2004 and 2005—14 percent—is due to the add-on payment mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implemented by CMS in 2005. The MMA mandated shifting some of the profits from dialysis drugs to an add-on payment to the composite rate in 2005. The MMA also lowered the payment rates for most dialysis drugs closer to the prices provider paid in 2005. Spending for dialysis drugs grew much more rapidly—15 percent per year— than the growth in the patient population between 1996 and 2004. This is due to increases in the volume of dialysis drugs provided to patients and price increases for non-erythropoietin drugs. Drug payments declined by about 10 percent between 2004 and 2005 because of the MMA's changes in drug payment rates.

Although payments for dialysis drugs declined between 2004 and 2005, MedPAC's analysis suggests that the volume of drugs (in terms of the units furnished to beneficiaries) continued to increase for most dialysis drugs. Payments for dialysis drugs declined because the unit price Medicare paid for dialysis drugs declined between 2004 and 2005 due to changes mandated by the MMA. Our calculations find that erythropoietin volume increased by 2 percent and the volume of the other leading drugs increased by 7 percent in 2005.

**Figure 1. Medicare's payments to freestanding dialysis facilities have steadily increased**

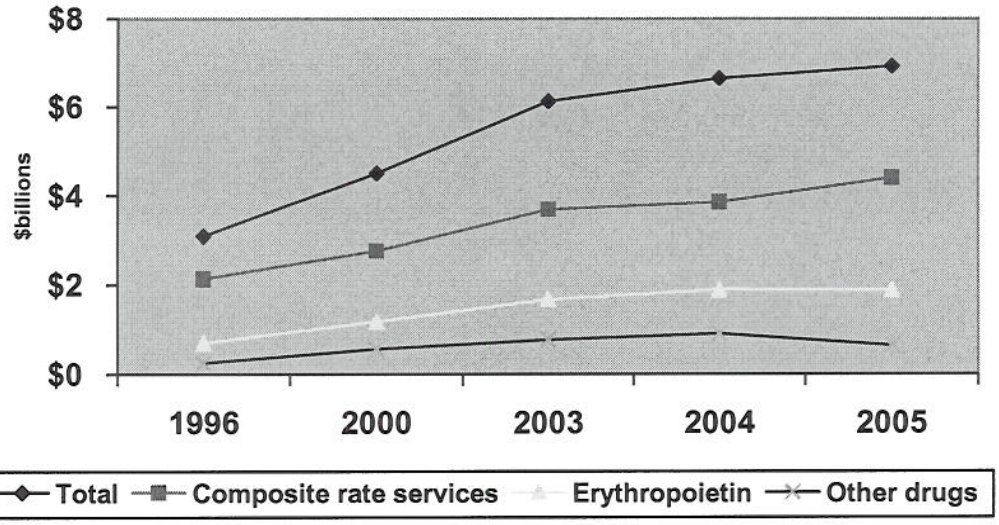
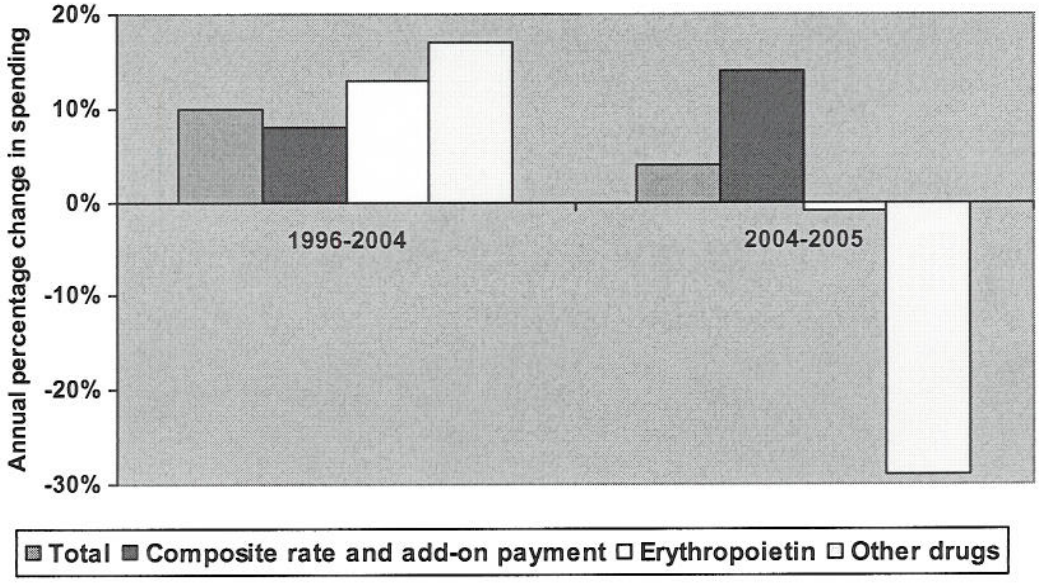



**Figure 2. The MMA increased the annual growth in spending for composite rate services and decreased spending for dialysis drugs**




Source: Compiled by MedPAC from 1996, 2000, 2003–2005 outpatient dialysis claims from CMS.

## Why did providers increase the volume of dialysis drugs and is all of the growth in volume appropriate?

Use of dialysis drugs has grown for two reasons. First, the drugs—including erythropoietin, iron supplements, and vitamin D analogs—effectively treat conditions that result from the loss of kidney function, such as anemia and bone disease. The use of many of these medications has enhanced the quality of care furnished to dialysis patients.

However, some researchers have reported that erythropoietin use varies among providers and suggested that providers could furnish erythropoietin more efficiently. Thamer et al. (2007) concluded that, compared with other facility types, large for profit chains administered higher erythropoietin doses and higher dose increases.[1] Pizzi et al. (2006) estimated net savings (of $257 per patient per month) could be achieved by using an alternative mix of erythropoietin and intravenous iron.[2] In addition, randomized clinical trials have found adverse events among patients with chronic kidney disease who received a greater dose of erythropoietin to achieve a higher hemoglobin level (Singh et al. 2006).[3,4]

Paying according to the number of units given to patients means that providers have an incentive to provide more units (as long as Medicare's payment exceeds their costs). In addition, the profitability of most drugs under the pre-MMA payment method gave providers an incentive to use more. In 2005, the new drug payment method reduced but did not eliminate the profitability of drugs. Medicare's payment rate for the top dialysis drugs exceeded the average sales price in 2005 (MedPAC 2007).[5,6]

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1 Thamer, M., Y. Zhang, J. Kaufman, et al. 2007. Dialysis facility ownership and epoetin dosing in patients receiving hemodialysis. *JAMA* 297, no. 15 (April 18): 1667–1674.

2 Pizzi, L. T., N. M. Patel, V. M. Maio, et al. 2006. Economic implications of non-adherence to treatment recommendations for hemodialysis patients with anemia. *Dialysis & Transplantation* 35, no. 11: 660–671.

3 Hematocrit measures a patient's anemia status by determining the percentage of red blood cells in the bloodstream.

4 Singh, A. K., L. Szczech, K. L. Tang, et al. 2006. Correction in anemia with epoetin alfa in chronic kidney disease. *New England Journal of Medicine* 355, no. 20 (November 16): 2085–2098.

Historical trends in the use of erythropoietin demonstrate the concerns about paying for profitable services on a per unit basis. After CMS changed its method of paying for erythropoietin from a relatively fixed payment per administration (of erythropoietin) between 1989 and 1991 to a per unit basis after 1991, per patient use of the drug substantially escalated—8 percent annually between 1991 and 2004 (from 7,100 units per week to 20,100 units per week) (USRDS 2006).[7]

As we discuss in more detail later in this letter, broadening the payment bundle and including drugs and other commonly furnished services might create more incentives for providers to furnish these services more efficiently.

## The Medicare margin for outpatient dialysis services

Each year, the Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments for composite rate services and dialysis drugs with providers' Medicare-allowable costs. The latest and most complete data available on freestanding providers' costs are from 2005.

As we describe in our March 2007 report, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs is 8.4 percent in 2005, after an audit correction (Table 1).[8] The aggregate margin for the large dialysis organizations (LDOs) is greater than the margin for all other freestanding facilities (10.7 percent versus 2.6 percent, respectively). LDOs account for about 72 percent of Medicare's spending for dialysis services among freestanding facilities.

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5 Average sales price (ASP) represents the amount drug manufacturers receive for their product. CMS calculates ASP using data submitted quarterly by pharmaceutical manufacturers and is net of rebates and discounts offered to purchasers by the manufacturers.

6 Medicare Payment Advisory Commission. 2007. *Medicare payment policy.* Washington, DC: MedPAC.

7 United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2006. *USRDS 2006 annual data report.* Bethesda, MD: NIDDK.

8 The Commission determines payment margins using the results of CMS's 2001 audit of freestanding providers' cost reports. The audit process generally lowers the cost per treatment and thus raises the margin. We describe this correction in our March 2007 report. The Medicare margin without the audit correction is 5.5 percent in 2005.

This finding stems from differences in the cost per treatment and the share of total payments from dialysis drugs. LDOs have lower cost per treatment, on average, than their counterparts. Our regression analysis indicates that total cost per treatment was 6 percent lower for the LDOs than their counterparts after adjusting for patient case mix and other facility-level characteristics. In addition, LDOs derived a greater share of dialysis payments from dialysis drugs, which were more profitable than composite rate services in 2005, than non-LDOs.

Based on the 2005 payment and cost data, we estimate that the 2007 aggregate margin will be 4.1 percent. This estimate reflects the Congress's update of the composite rate in 2006 (by 1.6 percent) and in 2007. Beginning on April 1, 2007, the Tax Relief and Health Care Act of 2006 updates the composite rate by 1.6 percent. This estimate also reflects the update of the add-on payment in 2006 and 2007.

**Table 1. Medicare margin in 2005 varies by type of freestanding provider**

| Provider type | Percent of spending by freestanding facilities | Medicare margin in 2005 |
|---|---|---|
| All | 100% | 8.4% |
| LDOs | 72 | 10.7 |
| Non-LDOs | 28 | 2.6 |

Note: LDO (large dialysis organization). LDOs are: Fresenius, DaVita, Gambro, and Renal Care Group.

Source: Compiled by MedPAC from 2001 and 2005 cost reports and 2005 outpatient claims submitted by facilities to CMS.

## Modernizing the outpatient dialysis payment system

In our March 2001 report, the Commission recommended that the Congress broaden the payment bundle to modernize the outpatient dialysis payment system. Medicare would provide incentives for controlling costs and promoting quality care by broadening the payment bundle to include drugs, laboratory services, and other commonly furnished items that providers currently bill

separately and by linking payment to quality. A bundled rate would create incentives for providers to furnish services more efficiently. For example, a bundled rate would remove the financial incentive for facilities to overuse dialysis drugs under the current method. (However, a bundled payment might give some providers an incentive to stint, as we discuss below.)

A bundled rate would also simplify the outpatient dialysis system. The MMA created the add-on payment to the composite rate from some of the profits that Medicare previously paid providers under the pre-MMA drug payment method. The MMA requires that CMS update the add-on payment based on the previous year's increase in drug expenditures. Under a bundled rate, it would no longer be necessary for CMS to separately update the add-on payment to the composite rate.

There are several important design issues that will need to be addressed as the outpatient dialysis payment system is modernized. The first issue concerns determining the services to include in the expanded bundle. Along with widely used dialysis drugs and laboratory tests that are currently not covered by the bundle, policymakers should consider including other services needed by dialysis patients including:

- Nutritional therapy,
- Vascular access monitoring and surveillance services, and
- Vaccinations for influenza, pneumonia, and hepatitis C.

A broader bundle might give some providers an incentive to stint on care. Consequently, the Secretary will need to continue efforts to monitor, report on, and improve the quality of dialysis care in order to promote the delivery of clinically appropriate care. The Secretary should collect clinical information for each dialysis patient to reflect the services included in an expanded bundle. Currently, CMS collects dialysis adequacy and anemia status for all patients on the claims providers submit for payment. The Secretary might consider augmenting this information with patient-level information on:

- Nutritional, iron, and bone disease status, and other measures reflecting patients' clinical status;
- Use of the leading dialysis drugs, including erythropoietin and other erythropoiesis-stimulating agents, iron therapies, vitamin D therapies, alteplase, levocarnitine, and antibiotics;
- Occurrences of hospitalization and emergency department use;
- Cases of mechanical complications, such as thrombosis of the arteriovenous fistula in hemodialysis patients and intra-abdominal bleeding among peritoneal dialysis patients; and
- Cases of infection, such as septicemia, peritonitis, and methicillin-resistant staphylococcus aureus infections.

Under an expanded bundle, the Secretary will need to ensure that dialysis providers are not sending patients to other Medicare providers (such as outpatient hospital departments) for services covered under an expanded bundle. It will also be necessary to ensure that services covered under an expanded bundle are not obtained by patients under the Part D program. For example, Medicare covers doxercalciferol, a drug used to treat bone disease, under Part B when patients receive it intravenously and under Part D when patients receive it orally (by capsule). In addition, the Secretary will need to ensure that non-dialysis providers are not duplicating care, i.e., furnishing a service included in an expanded bundle.

Another design issue concerns equalizing the base rate between freestanding and hospital-based providers. Currently, Medicare pays 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. This payment method is not consistent with the principle of paying the costs incurred by efficient providers who furnish appropriate care, regardless of the care setting. Consequently, the Commission recommended that the Secretary should implement a uniform payment policy across settings.

Other design issues that policymakers will need to address when designing a bundled payment include:

- Determining the unit of payment, which is currently a single dialysis session. Changing the unit of payment to either a week or a month might give providers more flexibility in furnishing care.
- Adjusting for factors that affect the costs of efficient providers. Currently, CMS adjusts payment for composite rate services by patients' age and two measures of patients' body mass. To assure that payments remain adequate in the future, both MedPAC and the Secretary should continue to explore whether additional factors are needed to adjust payment for factors that affect efficient providers' costs. In addition, Medicare's current payment method pays the same rate for the different methods of dialysis: conventional (thrice weekly) hemodialysis, more frequent hemodialysis, and peritoneal dialysis.

Finally, under an expanded payment bundle (as well as under the current payment method), the Commission believes that it is important for Medicare's payment systems to give incentives to providers investing in quality. Consequently, the Commission has recommended payment for performance in the outpatient dialysis setting (along with other fee-for-service providers and Medicare Advantage plans). Outpatient dialysis care is ready for pay for performance:

- Well-accepted measures are available
- Systems are in place to collect data
- Data are available to risk-adjust measures.
- Providers can improve upon measures.

The Commission supports implementing quality incentives budget neutral by explicitly linking a small proportion of total payments from facilities and physicians providing outpatient dialysis services to their quality performance. Possible quality measures that the Secretary could use include: adequacy of dialysis, other measures of patients' clinical status, and occurrences of hospitalization, emergency department use, complications (such as thrombosis), and infections (such as septicemia and peritonitis).

If you have any questions regarding this correspondence, please do not hesitate to contact Dr. Mark Miller, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman