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Testimony

Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

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END-STAGE RENAL DISEASE

Medicare Should Pay a Bundled Rate for All ESRD Items and Services

Statement for the Record of A. Bruce Steinwald
Director, Health Care

GAO-07-1050T

Mr. Chairman and Members of the Subcommittee:

I am pleased to provide, as requested, a statement for the record on Medicare payments for certain drugs provided to patients with end-stage renal disease (ESRD), a condition of permanent kidney failure.[1] Through Medicare's ESRD benefit, patients receive a treatment known as dialysis, which removes excess fluids and toxins from the bloodstream. Patients also receive items and services related to their dialysis treatments, including drugs to treat conditions resulting from the loss of kidney function, such as anemia and low blood calcium. Detailed information on the prudence of bundling payments for all ESRD items and services and a recommendation to establish a bundled payment system as soon as possible are included in our report entitled *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*.[2] This report, along with a testimony statement, was released at a December 6, 2006, hearing of the full Committee on Ways and Means.[3] Today's statement highlights the information in that report and refers to information other witnesses presented at the hearing. The work we performed for the report was conducted in accordance with generally accepted government auditing standards.

[1]These drugs are covered under Medicare Part B, the part of Medicare that covers a broad range of medical services, including physician, laboratory, and hospital outpatient services and durable medical equipment. Part B-covered drugs are typically administered by a physician or other medical professional rather than by patients themselves. In contrast, drugs covered under the new prescription drug benefit, known as Part D, are generally self-administered by patients.

[2]GAO, *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*, GAO-07-77 (Washington, D.C.: Nov. 13, 2006).

[3]GAO, *End-Stage Renal Disease: Medicare Payments for All ESRD Services, Including Injectable Drugs, Should Be Bundled*, GAO-07-266T (Washington, D.C.: Dec. 6, 2006).

Revised Medicare Payment Provisions Do Not Eliminate Incentives to Overuse Certain Drugs Billed for Separately

The way Medicare currently pays for injectable drugs provided to patients during dialysis treatments helps explain the potential for these drugs to be overused. The Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, divides ESRD items and services into two groups for payment purposes. In the first group are dialysis and associated routine services—such as nursing, supplies, equipment, and certain laboratory tests. These items and services are paid for under a composite rate—that is, one rate for a defined set of services. Paying under a composite rate is a common form of Medicare payment, also known as bundling. In the second group are primarily injectable drugs and certain laboratory tests that were either not routine or not available in 1983 when Medicare implemented the ESRD composite rate. These items and services are paid for separately on a per-service basis and are referred to as "separately billable."

Over time, Medicare's composite rate, which was not automatically adjusted for inflation, covered progressively less of the costs to provide routine dialysis services, while program payments for the separately billable drugs generally exceeded providers' costs to obtain these drugs. As a result, dialysis facilities relied on Medicare's generous payments for separately billable drugs to subsidize the composite rate payments that had remained nearly flat for two decades. In addition, the use of the separately billable drugs by facilities became routine, and program payments for these drugs grew substantially. In 2005, program spending for the separately billable drugs totaled about $2.9 billion.

The effect of several legislative and regulatory changes since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[4] has been to raise the composite rate for dialysis services while reducing Medicare's generous payments for separately billable ESRD drugs. Under the first legislative change in 2005, Medicare expenditures for certain of these drugs dropped 11.8 percent. Under the current payment method—which for each drug equals the manufacturer's average sales price (ASP) plus 6 percent—Medicare's payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payment rates.

[4]Pub. L. No. 108-173, 117 Stat. 2066.

The ASP-based rates are an improvement over the pre-MMA method, as ASP is based on actual transactions. However, certain unknowns about the composition of ASP and the ASP-based payment formula make it difficult for CMS to determine whether the ASP-based payment rates are no greater than necessary to achieve appropriate beneficiary access. For one thing, CMS has no procedures for validating the accuracy of a manufacturer's ASP, which is computed by the manufacturer. For another, CMS has no empirical justification for the 6 percent add-on to ASP. Regardless of how payment for these drugs is calculated, as long as facilities receive a separate payment for each administration of each drug and the payment exceeds the cost of acquiring the drug, an incentive remains to use more of these drugs than necessary.

The ASP payment method is of particular concern with respect to Epogen®, which in 2005 accounted for $2 billion in Medicare payments and is Medicare's highest Part B expenditure drug.[5] Most ESRD patients receive injections of Epogen at nearly every dialysis treatment, and whether Epogen is being overused has been called into question by some experts. At the December 2006 hearing of the full Committee, expert witnesses discussed their study results regarding Epogen use. One study found that kidney disease patients who were given high levels of Epogen experienced a higher risk of cardiovascular events and mortality than those who received lower levels of the drug.[6] Another study found that Medicare spent at least a third more on Epogen—amounting to hundreds of millions of dollars—than it would have if the levels of Epogen administered were in line with practice guidelines recommended by the National Kidney Foundation.[7]

[5]Introduced in 1989, Epogen—the brand name for epoetin alpha—was an expensive breakthrough drug used to treat anemia in patients with ESRD. In treating anemia—a condition in which not enough red blood cells carry oxygen throughout the body—Epogen is used to achieve a certain level of hemoglobin, the part of the red blood cell that carries oxygen. The National Kidney Foundation develops guidelines on the optimal hemoglobin range.

[6]See Ajay Singh et al., "Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease," *The New England Journal of Medicine*, vol. 355, no. 20 (Nov. 16, 2006).

[7]See Laura Pizzi et al., "Economic Implications of Non-Adherence to Treatment Recommendations for Hemodialysis Patients with Anemia," *Dialysis and Transplantation*, vol. 35, no. 11 (November 2006).

Our own study found that Epogen use, which grew rapidly in the years before the MMA provisions took effect, continued to grow through the first half of 2006, although at a slower rate than previously. Epogen is the only product available in the domestic ESRD market for anemia management. However, the ASP method relies on market forces to achieve a favorable rate for Medicare. When a product is available through only one manufacturer, Medicare's ASP rate lacks the moderating influence of competition. The lack of price competition may be financially insignificant for noncompetitive products that are rarely used, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable adverse effect on Medicare spending.

Bundled Payment System for ESRD Services, Including Injectable Drugs, Would Promote Efficiency and Clinical Flexibility

Medicare's approach to paying for most services provided by health care facilities is to pay for a group—or bundle—of services using a prospectively set rate. For example, under prospective payment systems, Medicare makes bundled payments for services provided by acute care hospitals, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities. In creating one payment bundle for a group of associated items and services provided during an episode of care, Medicare encourages providers to operate efficiently, as providers retain the difference if Medicare's payment exceeds the costs they incur to provide the services. Medicare's composite rate for routine dialysis and related services was introduced in 1983 and was the program's first bundled rate.

Experts contend that a bundled payment for all dialysis-related services would have two principal advantages. First, it would encourage facilities to provide services efficiently; in particular, under a fixed, bundled rate for a defined episode of care,[8] facilities would no longer have an incentive to provide more ESRD drugs than clinically necessary. Second, bundled payments would afford clinicians more flexibility in decision making because incentives to prescribe a particular drug or treatment are reduced. For example, providers might be more willing to explore alternative methods of treatment and modes of drug delivery if there were no financial benefit to providing more drugs and services than necessary.

[8]In the case of the composite rate, one dialysis session constitutes an episode of care. Unlike this method, a newly designed payment bundle could define the episode of care more broadly. For example, the new payment bundle could cover dialysis and related items and services for 1 month.

In response to a congressional mandate that CMS study the feasibility of creating a bundled payment,[9] the agency issued a study in 2003 concluding that developing a bundled ESRD payment rate was feasible and that further study of case-mix adjustment—that is, a mechanism to account for differences in patients' use of resources—was needed. In the MMA, the Congress required CMS to issue a report and conduct a 3-year demonstration of a system that would bundle payment for ESRD services, including drugs that are currently billed separately, under a single rate.[10] Both the CMS report, due in October 2005, and the demonstration, mandated to start in January 2006, are delayed.

Any payment changes based on CMS's report or demonstration would require legislation, because the MMA specified that drugs billed separately in 2003 would continue to be billed separately and not bundled in the composite rate.[11] In light of the uncertain time frame for CMS's test of bundling and the need for explicit legislation, in our report we asked the Congress to consider establishing a bundled payment for all ESRD services as soon as possible. In our view, Medicare could realize greater system efficiency if all ESRD drugs and services were bundled under a single payment. A bundled payment would encourage facilities to use drugs more prudently, as they would have no financial incentive to use more than necessary and could retain the difference between Medicare's payment and their costs. To account for facilities' increased or decreased costs over time, a periodic reexamination of the bundled rate may be necessary. This would ensure that facilities would be paid appropriately and that Medicare could realize the benefit of any cost reductions.

Contacts and Acknowledgments

For more information regarding this statement, please contact A. Bruce Steinwald at (202) 512-7114 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Phyllis Thorburn, Assistant Director; Jessica Farb; and Hannah Fein made key contributions to this statement.

[9]Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, app. F, § 422(b) and (c), 114 Stat. 2763A-463, 2763A-515—2763A-517.

[10]Pub. L. No. 108-173, § 623(e)–(f), 117 Stat. 2066, 2315-17.

[11]MMA § 623(d)(1), § 1881(b)(13)(B), 117 Stat. 2314-15 (to be codified at 42 U.S.C. § 1395rr(b)(13)(B)).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

June 22,2007

The Honorable F. Pete Stark
Chairman, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter of June 18 regarding trends in dosing of erythropoiesis stimulating agents in the treatment of anemia associated with dialysis in patients with end-stage kidney disease. Your questions concern data presented in the 2006 Annual Data Report of the U.S. Renal Data System (USRDS). I have directed members of my staff with detailed knowledge of the USRDS to prepare the enclosed responses to your questions. The responses indicate that use of erythropoiesis stimulating agents has increased over the past 15 years and that patients undergoing dialysis display variation in their hemoglobin levels.

I welcome the opportunity to share information about NIDDK's research efforts with the Committee, and I hope that you find this information helpful.

Sincerely,

Griffin Rodgers

Griffin P. Rodgers, M.D., M.A.C.P.
Director

Summary of NIDDK Responses to Questions on the United States Renal Data System

1. How are patients distributed by mean monthly hemoglobin (USRDS Chart 5.27)? What percentage of patients exceed the recommended maximum hemoglobin (Hb) of 12 grams per deciliter (g/dl)? What percentage of patients are below Hb of 10 g/dl. How have those trends changed over time?

In general, the percentage of patients with hemoglobin levels lower than 10 g/dl has declined, while the fraction of patients with hemoglobin levels above 12 g/dl has increased over time. By 2005, over half of patients had hemoglobin levels of 12.0 g/dl or greater. About 6 percent were below 10 g/dl.

2. How has mean EPO dose per week changed over time (USRDS Chart 5.30)?

Between 1991 and 2005, the average weekly dose of EPO more than doubled.

3. Page 198 of the 2006 USRDS Annual Report states, "We assessed provider practice patterns on dosing changes and found that DaVita tends to adjust the least and DCI the most when hemoglobin levels exceed 12–13 g/dl." How was this assessment conducted? What information was reviewed? Did NIH review anemia management guidelines? In what manner does DaVita make adjustments as compared to DCI? How do the other chains, such as Fresenius, compare?

This assessment examined patient months in which hemoglobin levels exceeded 12 g/dl, and determined the frequency with which such patients subsequently had their EPO dose reduced by at least 12.5 percent. Dialysis providers made appropriate dose reductions in about half of cases; frequency ranged from 55.2 percent for Gambro to 44.3 percent for Davita.

4. How does patient hemoglobin vary across dialysis centers (USRDS chart 10.21)? Which chains have the most patients exceeding Hb of 12 g/dl? Which chains have the largest proportion of patients within the target range of 10 to 12 g/dl?

The percentage of patients whose hemoglobin exceeds 12 g/dl varies widely across dialysis providers, ranging from 65 percent (Davita) to 20 percent (DCI) The chains with the largest proportion of patients within the target range of 10–12 g/dl are DCI (65 percent) and National Nephrology Associates (54 percent).

5. What are the trends for Medicare spending on erythropoiesis stimulating agents (ESAs) in recent year (USRDS Chart 11.26)? How does growth in spending on ESAs compare to spending on other parts of ESRD care? How do ESA costs per member month vary by dialysis chain?

The cost of services associated with dialysis increased by 72 percent between 1991 and 2004. The two primary components of this cost are the dialysis itself and erythropoiesis stimulating agents (ESA). Over this time period, dialysis costs increased 17 percent and ESA costs increased 235 percent. ESA costs by chain range from $654 per patient month for Gambro to $516 for hospital-based dialysis.

NIDDK Responses to Questions on the United States Renal Data System

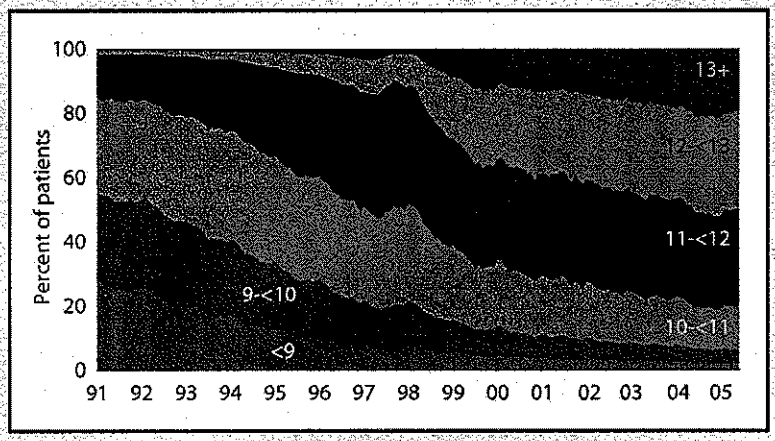
1. How are patients distributed by mean monthly hemoglobin (USRDS Chart 5.27)? What percentage of patients exceed the recommended maximum hemoglobin (Hb) of 12 grams per deciliter (g/dl)? What percentage of patients are below Hb of 10 g/dl. How have those trends changed over time?

Figure 5.27, shown on the next page, is from the 2006 Annual Data Report of the United States Renal Data System (USRDS). It shows the 15 year trend in average hemoglobin levels of kidney failure patients on hemodialysis whose treatment is reimbursed through Medicare. Normal hemoglobin values in adults range from 13.5 to 16.5 grams per deciliter (g/dl) of blood for men and 12 to 15.5 g/dl for women. Based on end-of-year figures for each year from 1991 to 2005, the following trends are displayed. In 1991, 52.4 percent of patients had a hemoglobin level of less than 10 g/dl, 16.4 percent of patients had achieved the target hemoglobin level of 11.0 g/dl, and 1.9 percent had a level of 12.0 or greater. By 2005, the percentage of patients with a hemoglobin level below 10.0 dropped to 6.4 percent, 30.5 percent of patients achieved the target hemoglobin level of 11.0, and the percent of patients with a level of 12.0 or greater increased to 50.1 percent.

The USRDS is a national data system that collects, analyzes, and distributes information about end-stage renal disease (ESRD) in the United States. The USRDS is funded directly by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in conjunction with the Centers for Medicare and Medicaid Services (CMS).

Patient distribution, by mean monthly hemoglobin (g/dl)

Figure 5.27



period prevalent dialysis patients with EPO claims; monthly hemoglobin includes all claims with a hematocrit value between 10 & 50; weekly EPO dose includes all claims for patients with an average number of administrations per month of ≤20. EPO doses prior to 2005 are adjusted for inpatient days.

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USRDS

Figure 5.27

2. How has mean EPO dose per week changed over time (USRDS Chart 5.30)?

Figure 5.30, shown on the next page (top), from the 2006 Annual Data Report of the USRDS, shows the EPO dosing and hemoglobin experience of new patients during the 6 months following the initiation of dialysis. These analyses are based on billing data, therefore, only patients for whom Medicare was the primary payer are included.

The left panel shows EPO dosing during the first 6 months following initiation of hemodialysis by year. For patients who started dialysis in 2000, the average weekly EPO dose in the first month was 12,298 units. This increased to 19,392 units in the second month and gradually decreased to 17,055 by the sixth month. The same pattern is seen in 2002 and 2004, although the EPO dose levels are higher in these years. The first, second, and sixth month weekly doses were 14,377, 22,738, and 18,495 units in 2002, and 16,783, 21,086, and 20,801 units in 2004. The maximum weekly dose occurred in the third month of 2004 and was 25,635 units.

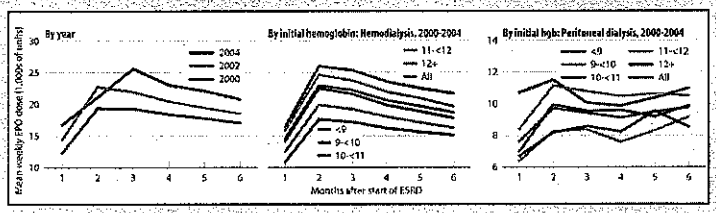
The center panel shows EPO dosing as it relates to the patients' hemoglobin levels at the initiation of hemodialysis. Patients with the lowest initial hemoglobin levels had the highest levels of EPO dosing. For example, patients with less than 9 g/dl had first, second, and sixth month average EPO doses of 16,383, 26,006, and 21,672 units. EPO dose levels with patients with initial hemoglobin levels of greater than 12 g/dl were 10,858, 17,603, and 15,092 over the same time period.

The right panel shows EPO dosing as it relates to the patients' hemoglobin levels at the initiation of peritoneal dialysis.. EPO dosing levels were approximately one-half the amount as for hemodialysis patients. As with hemodialysis patients, higher doses were given to those patients with the lowest starting hemoglobin levels.

Figure 5.28, shown on the next page (bottom), illustrates the overall trend in average weekly dose of EPO from 1991 to 2005. In 1991, the average weekly dose was 8,184 units. By 2005, the weekly dose doubled to 18,673 units.

Anemia treatment in incident dialysis patients, by modality & initial hemoglobin level: mean EPO dose per week

Figure 5.30



Incident dialysis patients with a first EPO claim within the first 30 days of the ESRD start date & at least one EPO claim in each of the first six months. Graphs by modality: 2000–2004 combined. Hemoglobin group determined by the patient's hematocrit on the Medical Evidence form. EPO doses adjusted for inpatient days.

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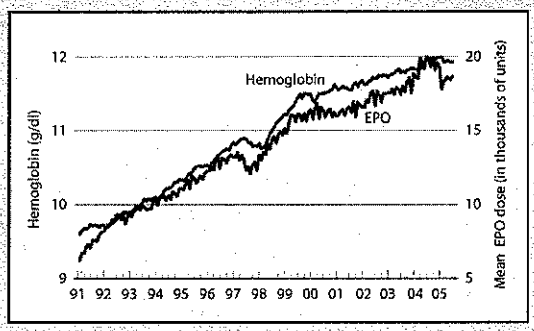
Figure 5.30

Mean monthly hemoglobin & mean EPO dose per week

Figure 5.28



period prevalent dialysis patients with EPO claims; monthly hemoglobin includes all claims with a hematocrit value between 10 & 50; weekly EPO dose includes all claims for patients with an average number of administrations per month of ≤20. EPO doses prior to 2005 are adjusted for inpatient days.

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Figure 5.28

3. Page 198 of the 2006 USRDS Annual Report states, "We assessed provider practice patterns on dosing changes and found that DaVita tends to adjust the least and DCI the most when hemoglobin levels exceed 12–13 g/dl." How was this assessment conducted? What information was reviewed? Did NIH review anemia management guidelines? In what manner does DaVita make adjustments as compared to DCI? How do the other chains, such as Fresenius, compare?

It is expected that a reduction in EPO dose should occur following a month in which the hemoglobin level exceeds the K/DOQI (Kidney Disease Outcomes Quality Initiative) upper limit of the target range—12 g/dl. The manufacturer recommends reducing the dose of EPO by 25 percent when hemoglobin is rising and approaching this limit. Dose and hemoglobin data used here—derived from the Medicare billing data—contain only monthly detail, and because dose adjustments can occur at any time during a given month, a monthly dose reduction of 12.5 percent was used to define an appropriate response. For each month in which an EPO claim reported hemoglobin exceeded 12 g/dl, the following month's EPO claim was examined for a dose reduction of at least 12.5 percent. If the reduction was found, this was judged to be an appropriate response.

Based on the definition above, about 50 percent of all potential response months resulted in an appropriated dose reduction. As shown in Figure 10.16, from the 2006 USRDS Annual Data Report, the results by chain affiliation were as follows:

- Gambro – 55.2 percent
- DCI – 54.1 percent
- Fresenius – 51.1 percent
- Renal Care Group – 49.5 percent
- National Nephrology Associates – 48.6 percent
- Non chain units – 46.6 percent
- Hospital based units – 45.5 percent
- DaVita – 44.3 percent

Because this analysis was based only on observational billing data, it is not possible to determine the manner, or process, by which adjustments are made. The enclosed peer reviewed version of this analysis was published in the January issue of the *American Journal of Kidney Diseases*. The citation for this analysis is as follows: Collins AJ, Ebben JP, and Gilbertson DT. EPO Adjustments in Patients with elevated Hemoglobin Levels: Provider Practice Patterns Compared with Recommended Practice Guidelines. *Am. J. Kidney Dis.* 49:135–142, 2007.

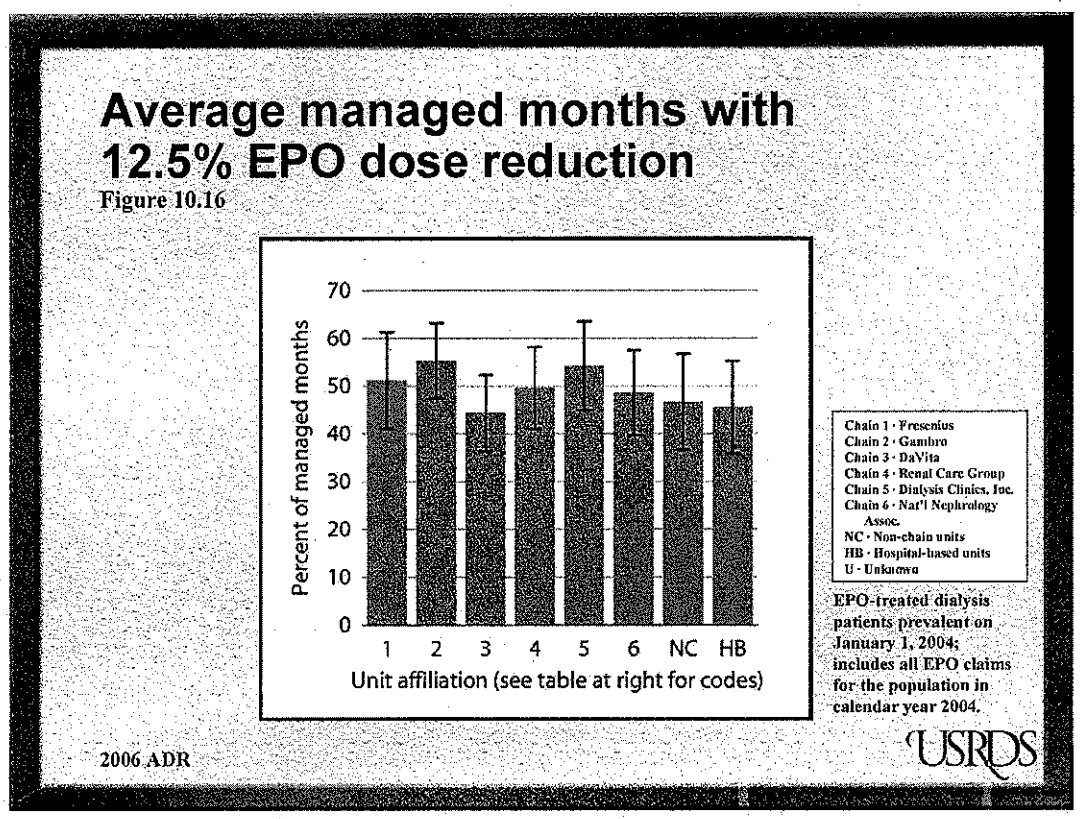
Average managed months with 12.5% EPO dose reduction
Figure 10.16
Percent of managed months
70
60
50
40
30
20
10
0
1
2
3
4
5
6
NC
HB
Unit affiliation (see table at right for codes)
Chain 1 · Fresenius
Chain 2 · Gambro
Chain 3 · DaVita
Chain 4 · Renal Care Group
Chain 5 · Dialysis Clinics, Inc.
Chain 6 · Nat'l Nephrology Assoc.
NC · Non-chain units
HB · Hospital-based units
U · Unknown
EPO-treated dialysis patients prevalent on January 1, 2004; includes all EPO claims for the population in calendar year 2004.
2006 ADR
USRDS

Figure 10.16

4. How does patient hemoglobin vary across dialysis centers (USRDS chart 10.21)? Which chains have the most patients exceeding Hb of 12 g/dl? Which chains have the largest proportion of patients within the target range of 10 to 12 g/dl?

Figure 10.21 from the USRDS 2006 Annual Data Report shows the distribution of patients at various hemoglobin levels by chain. In descending order of frequency, chains have the following percent of patient months greater than 12 g/dl:

- DaVita – 65.1 percent
- Gambro – 50.9 percent
- Renal Care Group – 47.3 percent
- Fresenius – 46.0 percent
- Hospital based – 43.1 percent
- Non chain – 42.4 percent
- National Nephrology Associates – 33.4 percent
- DCI – 20.3 percent.

In descending order of frequency, chains have the following percent of patient months in the target range of 10 to 12 g/dl:

- DCI – 64.8 percent
- National Nephrology Associates – 54.1 percent
- Non chain – 44.4 percent
- Fresenius – 43.6 percent
- Renal Care Group – 42.5 percent
- Hospital based – 40.6 percent
- Gambro – 40.3 percent
- DaVita – 27.5 percent.

These data represent aggregated monthly data. Most patients will be measured more than once, and some as many as 12 times. A patient could fall into one category for a few months, and one or more hemoglobin levels in other months. Therefore, these averages could be more accurately termed "patient months" of therapy. The data are self-weighting; that is, a patient with 12 months of hemoglobin data will contribute 12 data points to the final assessment, whereas a patient with only 3 months of data will contribute only 3 data points.

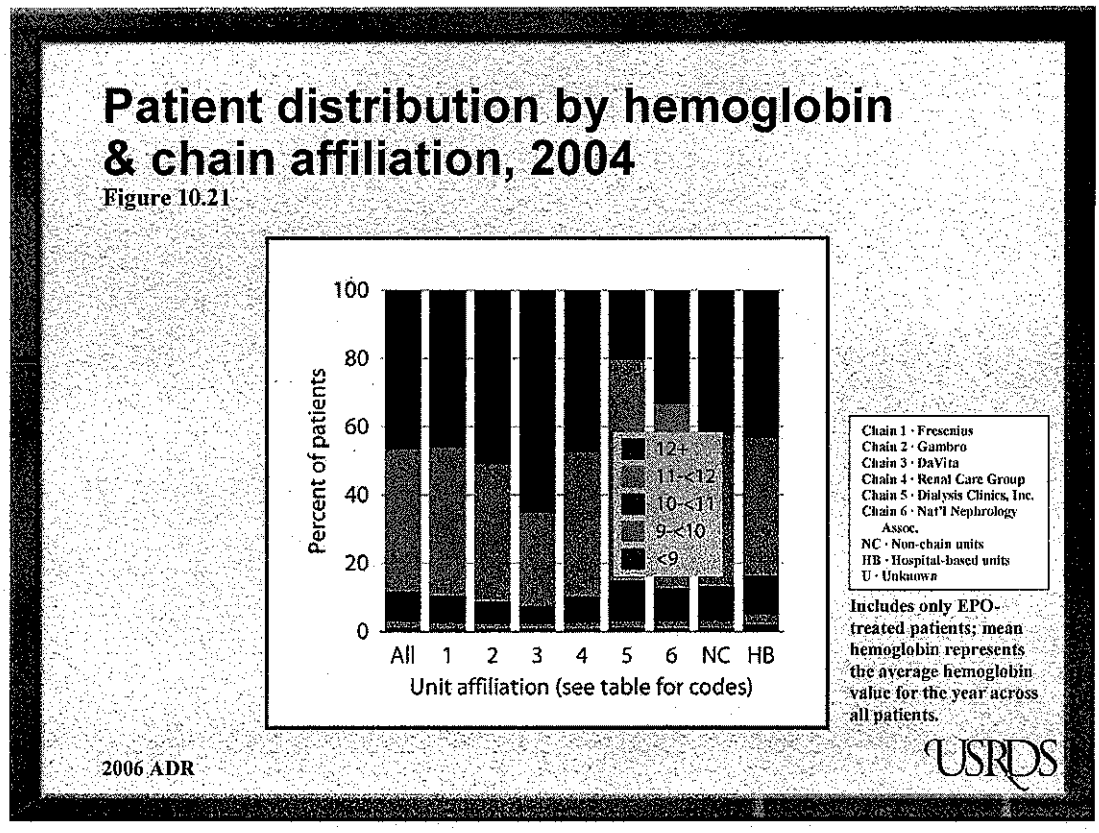
Patient distribution by hemoglobin & chain affiliation, 2004
Figure 10.21
100
80
60
40
20
0
Percent of patients
12+
11-<12
10-<11
9-<10
<9
All 1 2 3 4 5 6 NC HB
Unit affiliation (see table for codes)
Chain 1 · Fresenius
Chain 2 · Gambro
Chain 3 · DaVita
Chain 4 · Renal Care Group
Chain 5 · Dialysis Clinics, Inc.
Chain 6 · Nat'l Nephrology Assoc.
NC · Non-chain units
HB · Hospital-based units
U · Unknown
Includes only EPO-treated patients; mean hemoglobin represents the average hemoglobin value for the year across all patients.
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Figure 10.21

5. What are the trends for Medicare spending on erythropoiesis stimulating agents (ESAs) in recent year (USRDS Chart 11.26)? How does growth in spending on ESAs compare to spending on other parts of ESRD care? How do ESA costs per member month vary by dialysis chain?

Services provided as part of a dialysis session include dialysis, ESAs, intravenous iron, intravenous vitamin D, other injectibles, and laboratory procedures otherwise covered by the composite rate. In 1991 these services averaged $1,244 per patient month. By 2004, this had increased by 72 percent to $2,134. The two major cost components of the dialysis session are dialysis and ESA. Dialysis increased by 17 percent, from $970 to $1,135, whereas ESAs increased by 235 percent, from $173 to $580. ESAs accounted for 14 percent of dialysis-related costs in 1991 and 27 percent in 2004.

Medicare expenditures for ESAs per patient month by chain affiliation are as follows (in descending order), and are also illustrated in Figure 11.26 (next page, top panel).

- Gambro – $654
- Renal Care Group – $606
- DaVita – $588
- Fresenius – $576
- DCI and independents – $550
- National Nephrology Associates – $543
- Hospital based – $516

More detail is provided in figure 11.28 (next page, bottom panel).

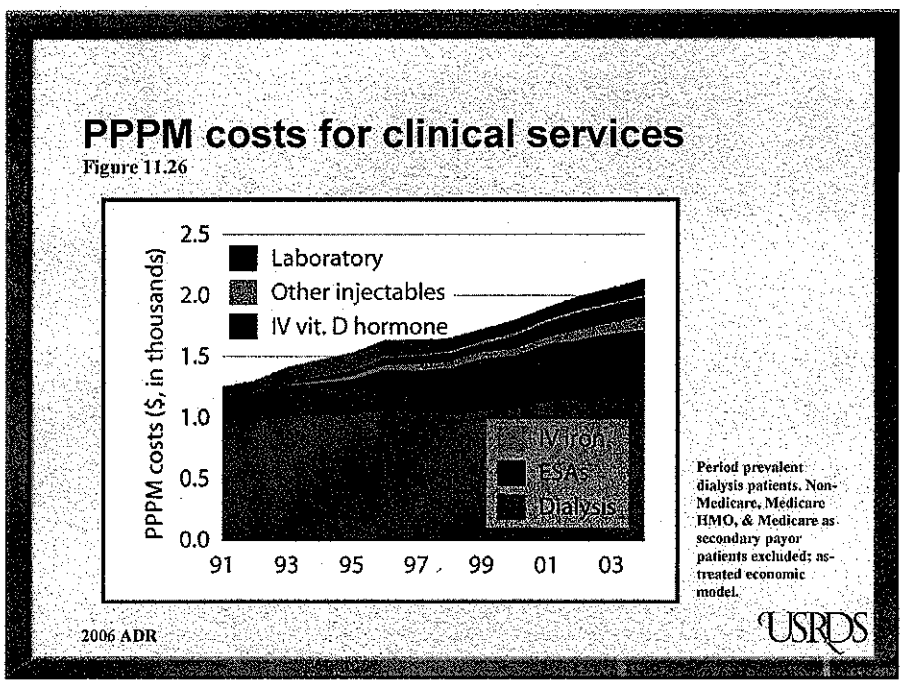

Figure 11.26

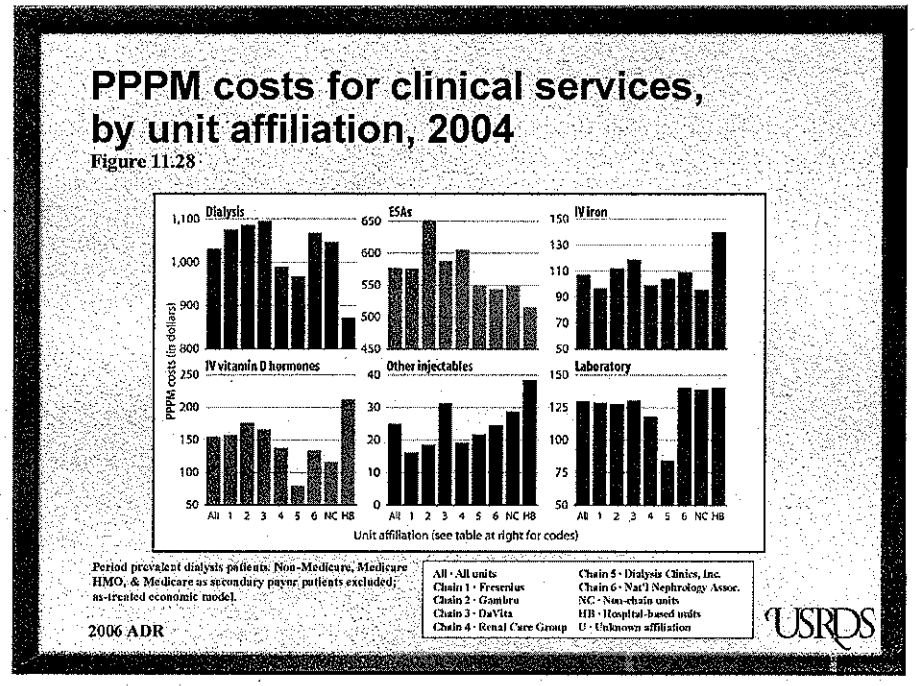

Figure 11.28

EPO Adjustments in Patients With Elevated Hemoglobin Levels: Provider Practice Patterns Compared With Recommended Practice Guidelines

Allan J. Collins, MD, FACP, James P. Ebben, BS, and David T. Gilbertson, PhD

Background: This study investigates provider practices regarding recombinant human erythropoietin (rHuEPO) dose when patient hemoglobin levels exceeded National Kidney Foundation–Dialysis Outcomes Quality Initiative target levels and reached 13 g/dL or greater (≥130 g/L).

Methods: The study population (N = 167,796) was hemodialysis patients prevalent on January 1, 2003, who were on renal replacement therapy at least 90 days with Medicare as primary payer and rHuEPO claims in 2 or more consecutive months. Patient characteristics were obtained from the Centers for Medicare & Medicaid Services (CMS) Medical Evidence Report, and comorbid conditions were determined from Medicare claims. Providers and rHuEPO claims were linked by using CMS-assigned provider numbers and the CMS Annual End-Stage Renal Disease Facility Survey. Between-provider differences in patient characteristics were examined by using chi-square test, and provider effect on appropriate response, by using logistic regression.

Results: DaVita's percentage of monthly claims for patients with hemoglobin levels of 13 g/dL or greater (≥130 g/L; 16.7%) and mean monthly rHuEPO dose (54,299 units) were highest. Dialysis Clinic Inc's percentage of such claims (2.0%) and mean monthly dose (38,687 units) were lowest. Dialysis Clinic Inc, Fresenius, and Renal Care Group had the highest percentage of recommended dose adjustments (mean, 70% of units); hospital-based units had the lowest (59%). By adjusted odds ratio, adjustments were 20% more likely for Dialysis Clinic Inc, Fresenius, and Renal Care Group compared with DaVita, National Nephrology Associates, hospital-based units, and independents (17% to 28% less likely).

Conclusion: rHuEPO dose reduction practices are dependent on specific dialysis providers and whether units are hospital based or independent.

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INDEX WORDS: Hematocrit; hemodialysis (HD); hemoglobin; recombinant human erythropoietin.

The introduction of recombinant human erythropoietin (rHuEPO) into clinical practice for the treatment of anemia related to end-stage renal disease (ESRD) led to substantial improvements in hemoglobin levels.[1,2] The dramatic increase in mean hemoglobin levels from the early 1990s to 2003 is paralleled by similar increases in rHuEPO doses and iron management.[3]

Target hemoglobin levels became an important aspect of care in autumn 1997, with the introduction of clinical practice guidelines by the National Kidney Foundation under its Dialysis Outcomes Quality Initiative. These guidelines, which were developed from the US Food and Drug Administration (FDA) labeling indication for epoetin, intervention trials, and expert opinion, suggested a target hemoglobin level of 11.0 to 12.0 g/dL (110 to 120 g/L) with rHuEPO treatment.[4] Providers' ability to maintain hemoglobin levels within the target range has been a matter of concern, given natural variability and other clinical factors that interfere with rHuEPO effectiveness.[5,6] Centers for Medicare & Medicaid Services (CMS) payment policies requiring medical justification for rHuEPO treatment when hematocrit levels exceeded 37.5%, with possible auditing for repayment, also may have contributed to variability. Cross-sectional data gathered

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monthly indicate that approximately 30% of patients have hemoglobin levels less than 11 g/dL (<110 g/L), 36% have levels between 11 and 12 g/dL (110 to 120 g/L), and the remaining third have hemoglobin levels greater than 12 g/dL (>120 g/L). Although this overall distribution appears to be consistent month to month, few patients remain within a particular group, such that by year end, only 5% are still in their original groups.[5,6]

The increasing percentage of patients with hemoglobin levels exceeding the current National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (KDOQI) target level of 12 g/dL (120 g/L) has been accompanied by a decreased percentage of patients with hemoglobin levels less than 11 g/dL (<110 g/L).[7] These developments appear to be the result of many factors, including concurrent illnesses, fluid overload leading to hemodilution, and rHuEPO hyporesponsiveness. However, as reported by the US Renal Data System (see *Annual Data Report* chapters on providers and economic costs),[3] there is considerable variation among dialysis providers in the distribution of patient hemoglobin levels. The increasing percentage of patients with hematocrits greater than 39% has caused concern because findings in at least 1 clinical trial suggested that high hematocrits (close to 42%) may constitute a risk for vascular access thrombosis and potentially increased mortality.[8] The recommended hemoglobin level range was defined on the basis of clinical trials suggesting safety at lower levels, but providers may not always decrease doses accordingly. Lack of attention to these targets, particularly at the upper end of the range, may lead to overuse of rHuEPO, driving hemoglobin to higher levels and overshooting the target range.

Recently, a new policy for rHuEPO use was implemented by the CMS.[9] It requires reduction in payment for rHuEPO doses for patients with hematocrits of 39% or greater. It is unclear how frequently providers adjust doses and whether there are differences across large groups. In this study, we investigate provider practice patterns related to rHuEPO dose and its adjustment when patient hemoglobin levels were at least 13 g/dL (130 g/L), a level consistent with CMS monitoring policy for use by fiscal intermediaries.

METHODS

The study population (N = 167,796) consisted of hemodialysis patients prevalent on January 1, 2003, who had been receiving renal replacement therapy for at least 90 days as of January 1, 2003; had Medicare as primary payer; and had rHuEPO claims in at least 2 consecutive months. Patient characteristics (age, sex, race, primary cause of renal failure, and dialysis vintage) were obtained from the CMS Medical Evidence Report (CMS-2728). Comorbid conditions were determined from Medicare Part A institutional and Part B physician/supplier claims, using *International Classification of Diseases, Ninth Revision, Clinical Modification,* codes according to a previously described method.[10] Conditions characterized included atherosclerotic heart disease, congestive heart failure, cardiac arrhythmia, other cardiac disease, cerebrovascular accident/transient ischemic attack, peripheral vascular disease, chronic obstructive pulmonary disease, cancer (including melanoma, but not skin cancer), liver disease, and gastrointestinal bleeding.

All rHuEPO claims for the study population for 2003 were analyzed to characterize anemia management, with specific attention to claims with a reported hemoglobin level of at least 13 g/dL (130 g/L). For each such claim, the rHuEPO dose was compared with the dose reported on the rHuEPO claim for the next month. To reduce the potential for incomplete dosing information, only claims for months in which the patient was not hospitalized were considered. KDOQI guidelines and the FDA-approved manufacturer's recommendations for anemia management call for a dose reduction of 25% for patients with a hemoglobin level of at least 12 g/dL (120 g/L). Recognizing the difficulty maintaining levels at the upper end of the recommended range (12 g/dL [120 g/L]) without exceeding it and based on the new CMS payment policy, we used a cutoff point for dose reduction 1 g/dL greater than the recommended level. Because claims data generally yield rHuEPO dosing information for 1 claim per month, we could detect dosage changes only from one month to the next, but the dose could have changed at any time during the month. To accommodate this imprecision, we classified a month-to-month dose reduction of one half the guideline (ie, 12.5% reduction) as an appropriate response to a hemoglobin level of at least 13 g/dL (130 g/L).

Using the CMS-assigned provider number included on the rHuEPO claim and the CMS Annual ESRD Facility Survey, rHuEPO claims were linked to individual dialysis providers, which were analyzed by chain (DaVita, Dialysis Clinic Inc, Fresenius, Gambro, National Nephrology Associates, and Renal Care Group). Providers not part of a chain were classified as hospital based or independent, defined from the CMS facility survey. If CMS identified a unit as hospital based, we classified it as hospital based. If CMS identified a unit as freestanding and it was not a part of 1 of the major chains named, we classified it as independent. Provider numbers that could not be linked to ESRD Facility Survey data were classified as "unknown affiliation." Providers with fewer than 10 qualifying rHuEPO claims were excluded from analysis.

For each provider, a measure of anemia management was calculated as the number of appropriate responses (rHuEPO

dose reduction ≥ 12.5% in the month after a reported hemoglobin level of at least 13 g/dL [130 g/L]) divided by the number of claims with a reported hemoglobin level of at least 13 g/dL (130 g/L), for which an rHuEPO claim was present for the following month and the patient had no hospital days in either month. Results for individual providers were aggregated into the provider classifications described. Chi-square tests were used to examine differences in patient demographics and comorbid conditions between providers. A logistic regression model was used to examine the effect of provider on appropriate response (1 or 0), adjusted for patient age, sex, race, primary cause of renal failure, and 10 comorbid conditions.

RESULTS

As listed in Table 1, patient characteristics generally were consistent across provider groups, with some variation in racial mix. Statistical differences were not clinically significant because recommendations are irrespective of demographic variables. As listed in Table 2, comorbidity was very similar among provider groups; statistical differences among comorbid conditions were not clinically significant, with the possible exception of liver disease, for which values varied widely among providers. For each provider, mean rHuEPO dose in response to a reported hemoglobin level of at least 13 g/dL (130 g/L) was as follows: DaVita, 54,299 U/mo; independent, 49,634 U/mo; hospital based, 49,598 U/mo; Fresenius, 49,407 U/mo; Renal Care Group, 48,772 U/mo; Gambro, 42,629 U/mo; National Nephrology Associates, 41,992 U/mo; and Dialysis Clinic Inc, 38,687 U/mo. Each provider was significantly different from every other provider with the following exceptions: Fresenius versus Renal Care Group, Fresenius versus hospital based, Gambro versus National Nephrology Associates, and hospital based versus independent.

Table 3 lists the total number of qualifying rHuEPO claims and the percentage of claims with a reported hemoglobin level of at least 13 g/dL (130 g/L). DaVita units had the highest percentage (16.7%) of claims with high hemoglobin levels, and Dialysis Clinic Inc units had the lowest percentage (2.0%).

Figure 1 shows means and SDs of the anemia management measure (percentage of managed months) for the provider groups. There was considerable variation among provider groups; Dialysis Clinic Inc, Fresenius, and Renal Care Group had an average anemia management measure of more than 70% and hospital-based units had a measure of 59%. Error bars, representing SDs of the percentages of managed months, show the range of variation.

Figure 2 shows the distribution of the anemia management measure for individual units within each provider group. The width of the frequency distribution curves shows the variation. The peak of the curve represents the approximate mean, and the width represents the SD. For example, the curve for Renal Care Group peaks sharply at 70% to 80%, indicating close adherence to the guidelines, whereas the curve for Dialysis Clinic Inc has a very broad peak, stretching from 60% to 70% to more than 90%, indicating a more varied adherence.

Figure 3 shows results of logistic regression analysis of the anemia management measure. In response to high hemoglobin levels, rHuEPO dose reductions were 20% more likely to occur in Dialysis Clinic Inc, Fresenius, and Renal Care Group units than Gambro units. Dose reductions were significantly less likely to occur in DaVita (19%), National Nephrology Associates (20%), hospital-based units (28%), and independent units (17%) than Gambro units. The distribution of units adjusting doses based on recommended practice was broad, ranging from a low of 10% to 20% to a high of 90%. The odds of a provider reducing the rHuEPO dose by the KDOQI-recommended 25% was significantly lower for DaVita, National Nephrology Associates, hospital-based units, and independent units compared with Gambro units.

Mean monthly hemoglobin levels were stable during the course of the year, remaining within ±0.1 g/dL for each provider group (data not shown). SDs also were stable within provider groups, but there were differences in means and SDs between provider groups. The highest was DaVita at 12 ± 1.5, and lowest was Dialysis Clinic Inc at 11.4 ± 1.2.

Sensitivity analysis results show that the effect of specifying a dosage percentage reduction less than the recommended 25% is to shift distributions to the right, with little or no effect on the shape of the distribution. Similarly, specifying a larger percentage of change shifts the distribution to the left with little or no effect on the shape.

Table 1. Patient Characteristics

Characteristic	All	DaVita	DCI	Fresenius	Gambro	NNA	RCG	Hospital	Independent	Unknown
No. of patients	167,796*	25,025	7,638	47,585	25,382	3,160	13,372	20,496	35,794	1,425
Age, y										
Median	64.0	63.0	63.0	64.0	64.0	64.0	64.0	66.0	65.0	65.0
Mean	61.9	61.4	60.9	61.6	61.9	61.9	61.5	62.8	62.3	62.2
SD	15.3	15.2	15.5	15.0	15.2	14.9	15.5	15.9	15.3	16.2
Distribution (%)										
0-19	0.3	0.3	0.4	0.2	0.2	0.1	0.3	0.8	0.2	1.7
20-44	14.3	14.7	15.6	14.4	14.3	13.9	15.1	13.5	14.1	13.5
45-64	36.4	37.2	37.7	37.4	36.6	37.7	36.3	33.0	35.2	34.0
65-74	25.9	26.3	25.2	26.3	25.7	25.4	25.7	26.0	25.8	25.8
≥75	23.1	21.6	21.1	21.6	23.2	22.9	22.7	26.7	24.7	25.0
Sex (%)										
Male	52.3	52.7	51.5	52.1	52.3	51.2	51.9	53.4	52.6	52.0
Female	47.7	47.3	48.5	47.9	47.7	48.8	48.1	46.6	47.4	48.0
Race (%)										
White	53.0	51.0	48.4	52.3	47.2	49.0	55.5	60.7	57.3	62.0
Black	40.8	40.3	47.6	43.2	48.0	47.7	39.4	29.9	35.9	29.3
Native American	1.6	3.1	2.1	0.8	0.9	0.7	3.1	2.5	1.1	1.1
Asian	3.7	4.9	1.5	2.6	3.3	1.9	1.5	6.0	4.5	6.4
Other/unknown	0.9	0.7	0.4	1.1	0.7	0.7	0.4	0.9	1.1	1.3
Primary cause of renal failure (%)										
Diabetes	42.2	42.6	40.4	42.3	41.6	41.8	42.7	40.8	41.9	41.2
Hypertension	29.6	30.1	28.9	30.7	31.5	31.2	29.9	25.4	28.5	24.4
Glomerulonephritis	12.0	11.5	12.6	11.6	11.5	12.2	11.9	14.2	12.6	13.8
Other	12.8	12.2	14.4	12.1	12.3	12.0	12.5	15.4	13.5	15.0
Unknown	3.5	3.5	3.7	3.3	3.1	2.9	3.0	4.2	3.5	5.6
Vintage (y)	4.3 ± 4.2	4.2 ± 4.2	4.6 ± 4.6	4.3 ± 4.3	4.2 ± 4.1	4.2 ± 4.1	4.2 ± 4.3	4.3 ± 4.4	4.1 ± 4.2	4.1 ± 4.1

Note: Values expressed as mean ± SD or percent unless noted otherwise. All *P* less than 0.0001 for age, sex, race, and primary cause of renal failure, by chi-square test.
Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.
*The sum of patients for each provider type does not equal the total number because patients who switched providers were counted in each.

Table 2. Cumulative Comorbid Conditions

Condition	All	DaVita	DCI	Fresenius	Gambro	NNA	RCG	Hospital	Independent	Unknown
Atherosclerotic heart disease (%)	55.2	54.1	50.2	54.8	54.6	62.1	53.0	57.2	56.9	53.1
Congestive heart failure (%)	60.4	59.9	56.8	61.4	59.9	60.4	58.3	59.8	60.4	59.5
Cardiac arrhythmias (%)	42.2	42.1	41.3	41.3	42.7	40.5	39.4	43.5	42.9	42.3
Other cardiac disease (%)	53.7	53.4	51.6	54.4	53.4	56.6	52.9	52.9	53.8	51.1
Cerebrovascular accident/transient ischemic attack (%)	28.4	28.3	26.7	28.3	28.7	28.8	27.6	27.9	28.4	27.0
Peripheral vascular disease (%)	52.5	52.5	50.1	52.1	51.8	50.6	52.5	54.2	52.4	51.8
Chronic obstructive pulmonary disease (%)	27.3	26.5	26.7	27.2	27.3	27.3	26.8	27.6	27.4	30.1
Cancer (%)	12.9	12.7	12.7	12.8	12.5	12.3	11.8	14.4	13.8	13.0
Liver disease (%)	23.7	32.1	10.5	26.0	15.7	23.8	16.4	22.1	26.8	19.8
Gastrointestinal bleeding (%)	25.7	25.1	26.2	25.6	25.8	26.1	24.5	25.4	26.1	24.0

Note: Within each comorbid condition, all *P* less than 0.0001 by chi-square test.
Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.

DISCUSSION

The continued growth in rHuEPO dosing and the increase in hemoglobin levels have raised concerns among payers and policymakers that providers may not be achieving optimal anemia management. Monitoring of care under the ESRD Clinical Performance Measures Project[11] and the unit-level reports distributed under Medicare's Dialysis Facility Compare show that providers have varying percentages of patients who meet or exceed target hemoglobin levels. The US Renal Data System's *2004 Annual Data Report* shows that in some provider groups, at least half the patients have an average hemoglobin level of at least 12 g/dL (120 g/L) during the entire year.[3] Our study shows that some provider groups have a high percentage of patients with hemoglobin levels not only greater than 12 g/dL (>120 g/L), but greater than 13 g/dL (>130 g/L). In other groups, less than 8% of patients have a hemoglobin level of at least 13 g/dL (130 g/L). This wide variation in achieved hemoglobin levels suggests that some providers have targets different from those recommended in the KDOQI guidelines, which are consistent with FDA recommendations. Even within a single group of providers, there is a wide range of adjustment patterns, suggesting inconsistent adherence to the recommended dose modification.

A more detailed assessment indicates that provider practice patterns associated with rHuEPO dose reduction are highly dependent on the specific large dialysis organization and whether dialysis units are hospital based or independent. Although there are small differences in demographic characteristics of patients served by the individual dialysis chains, hospitals, and independent dialysis providers, DaVita, National Nephrology Associates, and hospital-based units appear to adjust doses 20% less than the reference chains and as much as 40% less than other large dialysis organizations. These findings are based on a minimal dose reduction of 12.5% across 2 months with a reported hemoglobin level of at least 13 g/dL (130 g/L). These minimal changes yielded, on average, a 70% rate of management (versus that recommended), but the variation is considerable. Results do not change across 3 months of claims.

We also found inverse relationships among the providers. For example, DaVita has the lowest number of managed months and the highest percentage of hemoglobin levels greater than 11 g/dL (>110 g/L), whereas Dialysis Clinic Inc has the highest number of managed months and lowest percentage of hemoglobin levels greater than 11 g/dL. Despite an inverse relationship between hemoglobin level greater than 13 g/dL (>130 g/L) and percentage of hemoglobin levels less than 11 g/dL (<110 g/L), the percentage of patients within the recommended hemoglobin level range of 11 to 12 g/dL (110 to 120 g/L) is highly dependent on the provider.[7] Dialysis Clinic Inc had the highest percentage of patients with levels within the recommended range and the lowest percentage with levels greater than 12 g/dL (>120 g/L). DaVita had almost 3 times as many patients with levels greater than 12 g/dL

Table 3. rHuEPO Claims

	All	DaVita	RCG	Fresenius	Hospital	Independent	Unknown	Gambro	NNA	DCI
Total claims	1,713,706	235,046	128,053	459,481	194,044	338,761	11,453	242,379	30,470	74,019
Claims with hemoglobin ≥ 13 g/dL										
No.	179,637	39,352	16,256	47,715	20,030	33,375	1,076	18,709	1,672	1,452
%	10.5	16.7	12.7	10.4	10.3	9.9	9.4	7.7	5.5	2.0

Note: To convert hemoglobin in g/dL to g/L, multiply by 10.
Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.

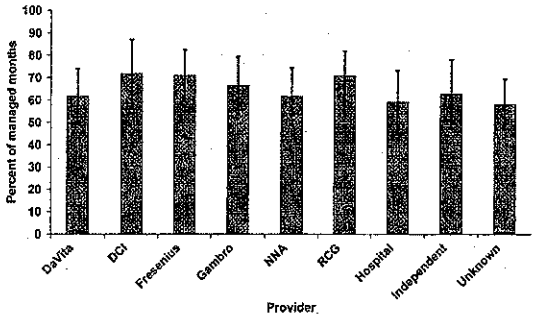

Figure 1. Anemia management measure (percentage of managed months) for the provider groups studied. Error bars are SDs. Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.

(>120 g/L), but the lowest percentage with levels less than 11 g/dL (<110 g/L). Provider practices appear to vary with regard to exceeding the guideline, raising the concern that practices focusing on a single component of the guideline recommendations (eg, hemoglobin level < 11 g/dL [<110 g/L]) may distort the more comprehensive FDA-approved package insert and KDOQI recommendations, which focus on keeping hemoglobin levels within 11 to 12 g/dL (110 to 120 g/L).

Reasons for the broad differences observed are not immediately apparent. One possibility is between-provider variation in the percentage of patients with medical indications for hemoglobin level to exceed recommended levels. A detailed analysis of diagnosis codes included on dialysis claims may help clarify this issue, but the justifications reported to fiscal intermediaries may not be passed on through the CMS system and may be unavailable for analysis. Also, parent corporations or owners may subject providers to performance measures linked to manager or staff compensation. Economic incentives to achieve certain targets may reduce the likelihood that rHuEPO doses would be changed, particularly if the percentage of patients for whom hemoglobin levels decreased to less than the KDOQI target is monitored, as opposed to the percentage of patients who were managed appropriately and those achieving a hemoglobin level of at least 11 g/dL (110 g/L). Provider efforts to reduce the percentage of patients with hemoglobin levels less than 11 g/dL (<110 g/L) may affect revenue streams. Finally, providers may be reluctant to reduce doses as recommended for fear that patients'

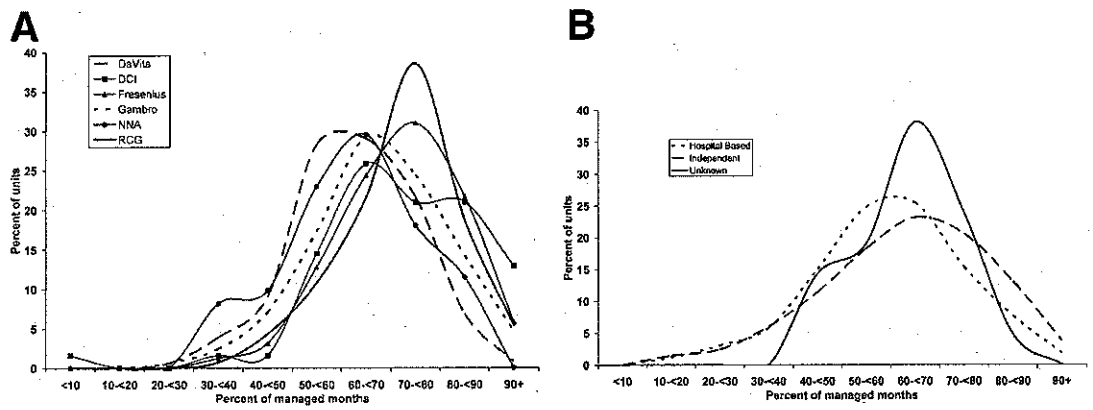

Figure 2. Distribution of anemia management by unit within provider group: (A) chain providers, (B) nonchain providers. Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.

levels may decrease further into and past the KDOQI targets, leading to cycling of patient hemoglobin levels as described by Fishbane and Berns.[12]

Clearly, provider practices are associated significantly with the likelihood of performing adjustments irrespective of age, sex, race, and comorbidity in the covered population. A more complete assessment of provider dosing practices is needed to determine whether these practices are associated with any positive, neutral, or adverse outcomes in patients. This complex assessment should address the greatest concerns, such as vascular access thrombosis and cardiovascular events, issues of concern in the normal-hematocrit trial by Besarab et al.[8] Because achieved hemoglobin levels may be highly confounded by disease burden, such advanced methods as a marginal structural model may be required.[13] Patient safety with hemoglobin levels exceeding the recommended range should be assessed further. Such analyses are beyond the scope of the current investigation, which focuses on describing patterns of practice and their potential variation.

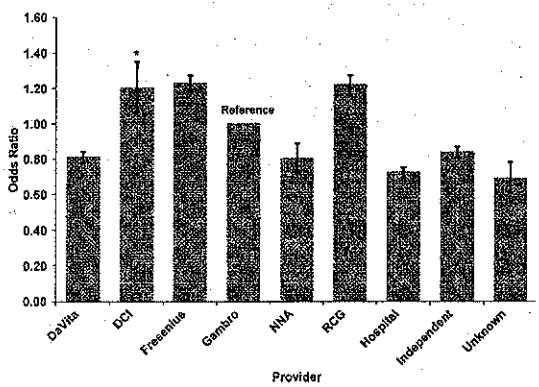

Figure 3. ORs for anemia management. $P < 0.0001$, except as noted. *$P = 0.0022$. Abbreviations: DCI, Dialysis Clinic Inc; NNA, National Nephrology Associates; RCG, Renal Care Group.

The limitations of our study deserve careful consideration. Only monthly hemoglobin levels are reported on rHuEPO claims. Providers may have access to multiple hematocrit values during the month that indicate a change in rHuEPO dose and allow for determination of the necessity of dose reductions for patients with a hemoglobin level that exceeds KDOQI targets. Because of hematocrit data limitations, determining the exact date during the month in which rHuEPO dose was decreased is difficult, and our ability to assess whether the total percentage of reduction was the suggested 25% is limited. To address this problem, we used a 12.5% reduction, reasoning that, on average, rHuEPO doses may change randomly throughout the month and the full amount of the change would not be reflected comparing it with the following month. Other unmeasured factors may influence a provider's likelihood of decreasing the rHuEPO dose, particularly in patients with high hemoglobin levels or with hospitalizations. Information regarding medical justifications offered for maintaining dosages in patients with higher hemoglobin levels is incomplete. To some ex-

tent, predictors of rHuEPO dose reduction show a greater likelihood in patients with cerebrovascular accidents and transient ischemic attacks. A more detailed analysis of indications for medical treatment exceeding the recommended levels is required to more accurately assess provider practices in rHuEPO dose reduction in patients with higher hemoglobin levels.

In summary, we assess the management of rHuEPO dose for patients with hemoglobin levels exceeding the KDOQI guidelines and find it to be highly related to the individual dialysis provider. In general, approximately 70% of providers' dialysis units adjust rHuEPO doses consistent with KDOQI guidelines and the FDA labeling instructions when hemoglobin levels exceed the recommended targets (13 g/dL [130 g/L]). The distribution is broad, suggesting that substantial improvement in the management of patients with elevated hemoglobin levels, with a decrease in rHuEPO dose, should be considered. Hemoglobin levels and rHuEPO dosing practices may change substantially with the recent changes in epoetin payment policies by CMS. Continued monitoring of these practices is warranted to determine whether providers are following recommended practices, thereby ensuring both safety and efficacy of anemia treatment for the dialysis population.

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1102 Longworth House Office Building
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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

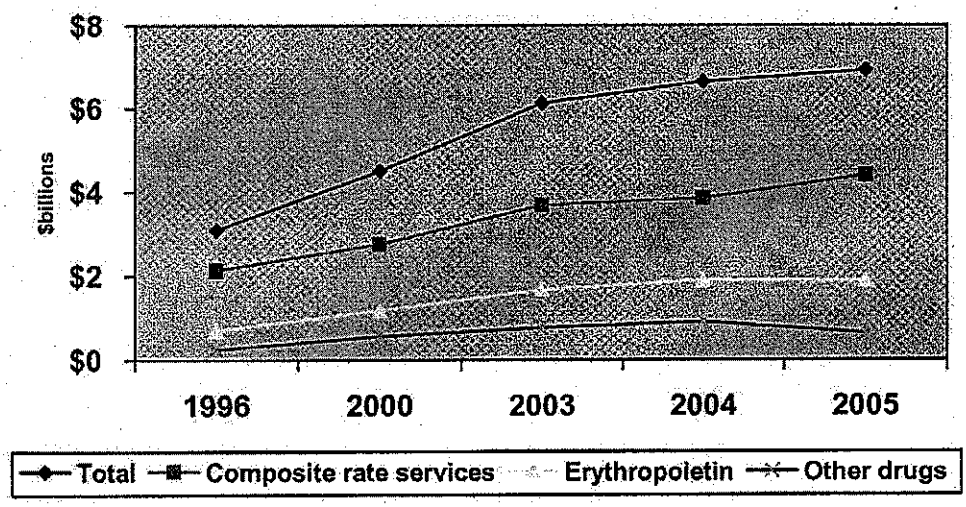
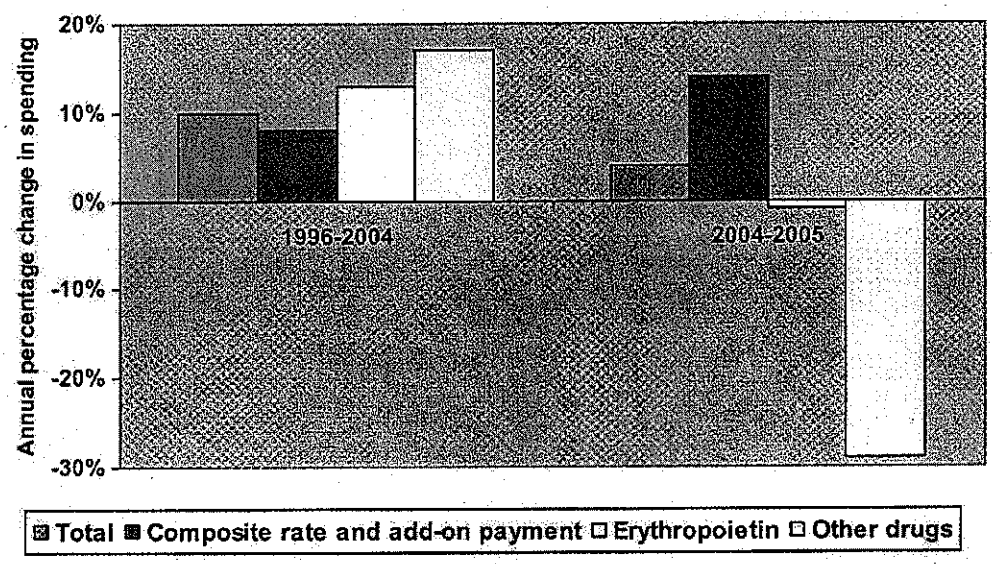


Figure 2. The MMA increased the annual growth in spending for composite rate services and decreased spending for dialysis drugs



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.

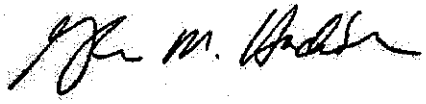
Finally, under an expanded payment bundle (as well as under the current payment method), the Commission believes that it is important for Medicare's payment systems to give incentives to providers investing in quality. Consequently, the Commission has recommended payment for performance in the outpatient 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

DEPARTMENT OF VETERANS AFFAIRS
UNDER SECRETARY FOR HEALTH
WASHINGTON DC 20420

JUN 2 2 2007

The Honorable Fortney Pete Stark
Chairman
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your interest in knowing how Veterans Affairs (VA) administers erythropoiesis stimulating agents (ESAs) in the treatment of anemia for End Stage Renal Disease (ESRD). In response to your questions, the following information is provided:

1. How many dialysis patients does the VA treat? What proportion of those patients receive ESAs via subcutaneous versus intravenous (IV) administration?

Response: There are 2064 patients on hemodialysis in the VA dialysis units. Seventy-six percent of these patients receive ESA via subcutaneous (SC) route and 24 percent through intravenous (IV) route.

2. Does subcutaneous administration of ESAs require a lower dose than IV administration in order to reach the same anemia management goal? How much lower of a dose? How does the frequency of the dose compare to IV administration?

Response: The dose of ESA administered via the SC route is 71 units per kg/treatment and by the IV route the dose is higher with 88 units/kg/treatment. There are two ESAs available in the United States, epoetin-alpha (sold as Epogen® and Procrit®, the latter which is only marketed for subcutaneous injection) and darbepoetin (sold as Aranesp®). There is only limited data available comparing intravenous and subcutaneous darbepoetin and the two routes of administration appear to be equivalent in terms of dosing and efficacy. For erythropoietin-alpha, the largest clinical trial, which was done in the VA, demonstrated that the dose required to reach the same target hematocrit was achieved using 25-33 percent less medication when using a subcutaneous route compared to the intravenous route (Kaufman JS et al, N Engl J Med 339:578-583, 1998).

3. To the extent VA administers ESAs subcutaneously, how much has the resulting decrease in doses lowered the cost of patient care?

Response: These calculations have not been formally done. In the document summarizing VA anemia research (enclosure 1), we estimated an annual savings of $2,987 to $4,095 per patient.

4. Has VA completed and published research discussing the lower doses and costs associated with subcutaneous administration of ESAs? What were the conclusions of that research?

Response: Enclosure 1 summarizes the research done in the VA discussing the lower doses and costs associated with SC administration of ESAs. We concluded that subcutaneous administration of epoetin in the hemodialysis population results in dose reductions of up to 32 percent compared to intravenous administration with annual savings of $2,987 to $4,095 per patient.

5. Do patients express discomfort or complain of pain when they receiving ESAs subcutaneously?

Response: There are two preparations of epoetin-alpha, one packaged in single dose vials and one packaged in multi-dose vials that also contain a preservative, benzyl alcohol that acts as a local anesthetic. In the VA clinical trial, the preparation with the preservative was used. In the clinical trial 86 percent of the patients rated the pain associated with subcutaneous injection as ranging from mild to absent while 14 percent of the patients had moderate pain.

6. Has the VA's use of subcutaneous administration of ESAs resulted in incidences of pure red cell aplasia (PRCA)? How rare of an occurrence is PRCA for patients receiving ESAs subcutaneously?

The Honorable Fortney Pete Stark

Response: Pure Red Cell Aplasia (PRCA) has primarily been reported with subcutaneous administration of a specific preparation, Eprex®, which is not available in the United States, although cases have been reported with all available ESAs. Eprex® is an epoetin-alpha similar to Epogen®, but has a different stabilizer and packaging. The risk of PRCA with Eprex® was thought to be related to the stabilizer (Tween-80) and the packaging in pre-filled syringes. Once these components were changed in 2004, the incidence of PRCA decreased markedly. The most recent estimates are as follows (Cournoyer et al, J Am Soc Nephrol 2004; 15:2728-2734):

Eprex® old preparation, SC	26.9 cases per 100,000 patient years
Eprex® old preparation, IV	0 cases per 100,000 patient years
Eprex® new preparation, SC	0.63 cases per 100,000 patient years
Epogen®, SC	0.2-0.7 cases per 100,000 patient years

Thank you for your interest and concern on behalf of veterans' health care.

Sincerely yours,

Michael J. Kussman, M.D.

Michael J. Kussman, MD, MS, MACP

Enclosure

Enclosure

VA has completed and published important research addressing the lower doses and costs associated with the subcutaneous administration of ESAs.

1. ***Kaufman JS, Reda DJ, Fye CL, et al: Subcutaneous compared with intravenous epoetin in patients receiving hemodialysis. Department of VA Cooperative Study Group on Erythropoietin in Hemodialysis Patients. N Engl J Med 339:578-583, 1998.*** In an unblinded trial conducted at 24 hemodialysis facilities at Veterans Affairs medical centers, 208 patients who were undergoing long-term hemodialysis were randomly assigned to receive epoetin intravenously (n =101) or subcutaneously (n = 107) (10). The dose was reduced until the hematocrit level was below 30%, then increased gradually until the hematocrit level was between 30% and 33%, an acceptable range according to recommendations by the Food and Drug Administration. The average dose over a 26-week maintenance period was compared between patients who received epoetin intravenously or subcutaneously. Data on discomfort associated with the route of administration were also collected. Data were collected from August 1994 to January 1997. Results indicated that the average weekly dose of epoetin was 32% lower (95% confidence interval [CI]: 14% to 50%) for patients who received subcutaneous epoetin, and that 86% of patients rated the pain associated with subcutaneous administration as absent to mild.

2. ***Kaufman JS for the Department of Veterans Affairs Cooperative Study Group on Erythropoietin in Hemodialysis Patients. Subcutaneous erythropoietin therapy: Efficacy and economic implications. Am J Kidney Dis 32:S1-S5, 1998.*** This research reviewed prior studies that suggested that lower doses of erythropoietin (rHuEPO) may be required to achieve a target hematocrit when the biologic is administered subcutaneously (SC) compared with intravenously (IV). A particular focus was on the Department of Veterans Affairs multicenter trial comparing the two routes of administration. The discussion noted that the specific mechanisms that result in the greater efficiency of the subcutaneous route are unknown but are probably related to the prolonged half-life of the hormone with subcutaneous administration. It was suggested that possible mechanisms resulting in greater efficiency with subcutaneous therapy include sustained stimulation of the erythroid progenitor cells, diminished inhibition of erythropoiesis by proinflammatory cytokines, and prevention of neocytolysis, the hemolysis of newly formed red blood cells. Further, it was concluded that because most hemodialysis patients in the United States are receiving rHuEPO by the intravenous route, switching to the subcutaneous route may result in significant cost savings for the health care system.

3. ***Hynes DM, Stroupe KT, Greer JW, et al. Potential cost savings of erythropoietin administration in end-stage renal disease. Am J Med. 2002; 112(3):169-175. (CSP 392 Economic Impact Study).*** Based on results found from the VA clinical trial CSP392, this study posed the question: if Medicare end stage renal disease patients had their anemia managed similar to the way VA patients were managed, what impact would there be on Medicare costs? Using Medicare data from 1997-1998 the research found that 91% of Medicare patients were receiving their erythropoietin IV. The research estimated that the Medicare End-Stage Renal Disease Program could save $47 to $142 million annually as 25% to 75% of patients switched to subcutaneous administration of epoetin, assuming that the dose reduction matched the 32% reduction in the Department of Veterans Affairs randomized controlled trial. Centers for Medicare and Medicaid Services (CMS) collaborated on this study with VA researchers.

4. ***Hynes, DM, Stroupe, K, Browning, M, Kaufman, J, Reda, D. Chronic Care Delivery in End Stage Renal Disease: Adherence to Clinical Guidelines for Anemia Management. American Journal of Kidney Diseases. 2006; 47(3): 455- 461.*** Using data from a multisite prospective observational study of 308 hemodialysis patients from 8 VA medical centers from 2001 to 2003, the study examined compliance with National Kidney Foundation–Dialysis Outcomes Quality Initiative (NKF-DOQI) erythropoietin administration guidelines across Veterans Affairs (VA) versus private-sector dialysis facilities and implications for erythropoietin dose, anemia management, and cost. The research found that erythropoietin was administered predominantly subcutaneously for 52% of patients in the eight VA units in the study versus 15% in private-sector facilities and estimated costs for erythropoietin were lower in the VA compared to the private sector. Anemia management was similar. The findings indicate that potential annual savings of $2,987 to $4,095 per patient exist if NKF-KDOQI guidelines are followed and subcutaneous administration of epoetin is used, assuming a Medicare-allowed rate of $10/1,000 units.

KAISER PERMANENTE®

June 22, 2007

The Honorable Pete Stark
Chairman, Health Subcommittee
Ways and Means Committee
U.S. House of Representatives
1135 Longworth House Office Building
Washington, DC 20515

Re: Kaiser Permanente Southern California (KPSC) Renal Program Experience with Bundled Payment and Subcutaneous Use of EPO

Dear Chairman Stark:

In response to an invitation from your staff to submit information for the subcommittee hearing on June 26th, Kaiser Permanente Southern California (KPSC) Region is providing information from our experience regarding: 1) subcutaneous administration of erythrocyte stimulating agents (ESAs) for the majority of our hemodialysis patients; 2) bundling of payment for hemodialysis and dialysis-related services; and 3) provision of short daily hemodialysis.

Based on our experience in southern California, we have found that subcutaneous administration of Epogen is an efficient method of delivery and can lower dosing levels and costs. We have also found that bundled payments are an effective way to pay dialysis centers and are consistent with both positive health outcomes for beneficiaries and efficient use of Epogen.

Use of Subcutaneous Epoetin

Following the release of the original National Kidney Foundation DOQI guidelines in 1997 which supported subcutaneous administration of epoetin, KPSC undertook a quality initiative to convert hemodialysis patients from intravenous to subcutaneous use. The program allowed for exceptions based on medical considerations and patient preference. Most hemodialysis patients chose subcutaneous administration, and we have continued to maintain the majority of them on subcutaneous administration (80% as of 12/31/2006). Importantly, we have found that when given medical and cost information, most hemodialysis patients prefer to receive subcutaneous epoetin – for many it is a welcome chance to reduce the cost of their treatments which they recognize as being very expensive.

We have found and reported that the dose required for subcutaneous epoetin in hemodialysis patients is about 28% less than for intravenous epoetin (*American Society of Nephrology* abstract, 2001). This is similar in magnitude to several other published reports.

In addition, all KPSC patients on peritoneal dialysis utilize subcutaneous epoetin.

Dialysis and Dialysis-related Services Bundling

There is currently much interest and debate surrounding proposals to combine payment for medications and laboratory testing into a "bundled" Medicare dialysis payment. Some believe that such a strategy could lead to adverse patient outcomes, and further, that any bundled payment should be stratified to increase payment for patients with multiple co-morbidities. In this light, we wish to make the committee aware of our successful experience in the bundling of payment for dialysis and dialysis-related services.

The majority of our hemodialysis patients are either insured by Medicare (primary or secondary), most under the Medicare Advantage program (Kaiser Permanente Senior Advantage), or are enrolled in commercial Kaiser Foundation Health Plan coverage. Therefore, we are the direct payers for hemodialysis services, much the same as traditional Medicare is for the majority of beneficiaries needing dialysis.

KPSC adopted a bundled payment model for dialysis in 1999. This bundled payment model is now used for 53 percent of our hemodialysis patients (1957 out of 3675 hemodialysis patients, as of June 20, 2007).

The services included in these contracts have varied over time, but now include the dialysis treatment, non-oral medications including EPO, iron and vitamin D sterols, monthly routine laboratory tests and additional, non-emergent laboratory tests. Payment levels are not risk stratified for co-morbid conditions or other factors. In one contract with a dialysis provider, each facility is eligible for a performance incentive payment linked to patient satisfaction and nephrologist satisfaction.

Our quality monitoring, through both our internal quality program and our dialysis provider's quality programs, indicate that our hemodialysis patients have very good outcomes. Measured outcomes include the adequacy of the dialysis treatments, anemia outcomes, mineral metabolism outcomes and patient satisfaction.

The majority of dialysis services for our 400+ peritoneal dialysis patients are provided internally, so we do not have experience in the bundling of payments to third party providers for this modality.

More Frequent Dialysis and Home Hemodialysis

Your staff also asked about the KPSC experience with more frequent dialysis, particularly as utilized for short daily home hemodialysis (SDHHD). KPSC is gaining experience with SDHHD, and our program, based at our Los Angeles Medical Center, has recently published their results, showing positive outcomes, including improved quality of life (*Hemodialysis International*, Volume 11, Issue 2, pp. 225-230, April 2007).

Thank you for your interest in some of the innovative programs we have at Kaiser Permanente. Please do not hesitate to contact Fish Brown in our Washington, D.C. office with additional questions, as we would be happy to provide whatever information we can to assist you and your staff.

Sincerely,

Peter Crooks, MD
Physician Director, Renal Program
Associate Medical Director of Operations
Kaiser Permanente Southern California