Monday, Monday
So good to me
Monday morning
It was all I hoped it would be
Oh, Monday morning
Monday morning couldn’t guarantee
That Monday evening you would still
Be here with me

John Phillips, “Monday Monday”
Following consolidation of Gambro dialysis units into DaVita, and of Renal Care Group units into Fresenius, the landscape of dialysis providers appears to have stabilized.

At the end of 2009, 122,216 prevalent patients were being treated by Fresenius in 1,742 units, 110,299 were receiving care in one of DaVita’s 1,556 units, and 13,023 patients were being treated by Dialysis Clinic Inc. (DCI), with 213 units. These three major providers manage the majority of the 5,760 dialysis units across the United States. Small dialysis organizations (SDOs), comprising 20–199 units, treated 44,793 patients in 605 units, while independent and hospital-based providers treated 58,090 and 38,596 patients in 848 and 796 units, respectively.

Recent clinical trials have reported adverse outcomes with hemoglobin levels above 11 g/dl. In 2011, the Food and Drug Administration (FDA) removed the target hemoglobin range of 10–12 g/dl from package inserts of erythropoiesis stimulating agents (ESAs), instructing that ESA treatment for dialysis patients be initiated when the hemoglobin falls below 10 g/dl, and that providers reduce or interrupt the ESA dose if the level approaches or exceeds 11 g/dl. In 2009, nearly one-fifth of dialysis patients treated with erythropoietin (EPO) — across providers — had a hemoglobin level exceeding 12 g/dl. The FDA’s “black box” warning is designed to encourage physicians to individualize ESA treatment in their patients, and should ultimately change ESA dosing patterns among dialysis providers, reducing the likelihood of ESRD patients reaching high hemoglobin levels.

The new prospective bundled dialysis payment system, also introduced in 2011, alters provider incentives for treatment. The effect of this system on patient treatment and outcomes, and of the FDA’s changes in the labeling for ESAs, will be examined in future ADRs.

To maintain optimal hemoglobin levels, it is important that patients have adequate iron stores. In 2009, 66 percent of prevalent dialysis were treated with Venofer and 20 percent with Ferrlecit; INFeD is used sparingly, in only 0.2 percent of patients. As noted in earlier chapters, the number of patients receiving a total iron dose of 2,700 mg or more over the first six month of dialysis has increased from 22 percent in 2000 to 40 percent in 2009. Adequate safety studies on the use of these large doses of IV iron have yet to be performed, limiting our ability to assess this major change in clinical practice.

This year we again examine preventive care services delivered by providers, focusing on diabetic care and vaccinations. Glycemic control (A1c) testing in diabetic patients differs by unit affiliation, with 63–65 percent of patients in Fresenius, DaVita, SDO, and independent units receiving four or more A1c tests during 2008–2009, compared to 42–47 percent of patients in hospital-based and DCI units. Just 56 percent of diabetic patients on dialysis receive two or more lipid tests, and fewer than one in three are tested four or more times; those treated in an independent or hospital-based unit are more likely to receive four or more tests than their counterparts in chain-owned or SDO units. These practice patterns may change based on results from the SHARP study, demonstrating reduced ath-
erosclerotic events when patients are treated with a combination lipid lowering therapy (Lancet, June 2011). Eye examinations are another important preventive care tool, used to detect diabetic retinopathy. Fewer than one in four prevalent dialysis patients with diabetes received an eye exam in 2008–2009. Rates of vaccination, both for influenza and for pneumococcal pneumonia, have improved over the years; patients dialyzing in units owned by DaVita are the most likely to receive these vaccinations.

Medicare payments vary considerably across provider groups. Per person per year (PPPY) expenditures for dialysis rose just 1.5 percent in 2009, to $17,851 overall, but ranged from a low of $17,016 in hospital-based units to a high of $18,717 in units owned by SDOs. PPPY costs for ESAs totaled $6,175 overall, and were again lowest in hospital-based facilities.

We conclude with an analysis of mortality and hospitalization ratios. Standardized hospitalization ratios (SHRs) and standardized mortality ratios (SMRs) in 2009 are similar across providers; SHRs, however, are slightly higher in independent facilities, while hospital-based facilities tend to have slightly higher SMRs. Among the large dialysis organizations, DCI continues to have the lowest statistically significant SHRs and SMRs. SDOs in the East North Central, Middle Atlantic, and New England census divisions have statistically significant higher SHRs. In hospital-based units, statistically significant higher SHRs and SMRs exist in the East South Central, South Atlantic, and West South Central divisions. The USRDS will continue to assess provider outcomes over time to determine areas for improvement.

Figure 10.1, see page 391 for analytical methods. CMS Annual Facility Survey, 2009.

<table>
<thead>
<tr>
<th>Large dialysis organizations (245,538 patients / 3,511 units)</th>
<th>SDOs (44,793 / 605)</th>
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<tbody>
<tr>
<td>DaVita (110,299 / 1,556)</td>
<td>Hospital-based (38,596 / 796)</td>
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<tr>
<td>Dialysis Clinic, Inc. (13,023 / 213)</td>
<td>Independent (38,090 / 848)</td>
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<tr>
<td>Fresenius (122,216 / 1,742)</td>
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<td>American Renal Assoc.</td>
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<td>Innovative Dialysis Systems</td>
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<td>Liberty Dialysis</td>
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<td>Dial. Corp. of America</td>
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<td>Renal Research Institute</td>
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Between 2004 and 2009, the number of dialysis units grew 41 percent in Network 9, and 44 percent in Network 14. In Network 2, in contrast, the number of units rose only 2 percent. Growth in the number of patients ranged from 12 percent in Network 2 to 27–30 percent in Networks 14, 15, 16, and 18.

In 2009, Fresenius and DaVita were the largest dialysis providers, with approximately 60 percent of all dialysis units and patients; units owned by DCI totaled 213, with just 3.4 percent of the total dialysis population. Small dialysis organizations (SDOs) — defined as those with 20–199 dialysis units — accounted for 11–12 percent of units and patients, and independently owned facilities accounted for 15 percent. Hospital-based facilities represented 14 percent of all dialysis units, and accounted for 10 percent of the dialysis population.

The percentage of units remaining under consistent ownership for five or more years was nearly 60 in 2009. Major unit purchases by DaVita and Fresenius in 2005 and 2006 reduced the proportions of their units with five or more years of ownership to 51 and 60 percent, down from approximately 70 percent in 2004 (2010 Annual Data Report). The most consistent ownership remains that of Dialysis Clinic, Inc., with nearly 90 percent of units in 2009 owned for five years or longer. » Figures 10.2–4: see page 391 for analytical methods. CMS Annual Facility Survey, 1988–2009.

### UNIT AFFILIATION

- **All**: All units
- **F**: Fresenius
- **DV**: DaVita
- **DCI**: Dialysis Clinic, Inc.
- **SDOs**: Small dialysis organizations (defined as 20–199 dialysis units; unit classification assigned by the USRDS)
- **Ind**: Independent units
- **HB**: Hospital-based units
In 2009, the proportion of EPO-treated prevalent dialysis patients with a hemoglobin of 10–<12 g/dl varied little by provider, ranging from 72 to 79 percent, and reaching 78 percent overall. Twenty-five percent of DCI patients had a hemoglobin greater than 12 g/dl, compared to 18–19 percent of those receiving treatment in Fresenius or independent units. Figure 10.5; see page 391 for analytical methods. Period prevalent dialysis patients, 2009.

In 2009, 20 percent of prevalent dialysis patients were treated with Ferrlecit, and 66 percent with Venofer; INFeD is now used sparingly, in only 0.2 percent of patients.

Choice of IV iron type varies considerably by provider. In units owned by DaVita and DCI, for example, 86–87 percent of patients receive Venofer, compared to 48–50 percent of patients treated in independently owned or hospital-based units. In these latter units, Ferrlecit is used by 37 and 28 percent of patients.

In the first six months of dialysis, the number of months in which patients receive IV iron is 4.6 overall, and slightly higher in for-profit units. The mean total IV iron dose is 2,348 mg overall, and highest in units owned by Fresenius, at 2,491. Figures 10.6–8; see page 391 for analytical methods. Period prevalent dialysis patients, 2009 (10.6); incident dialysis patients treated with EPO, 2009 (10.7–8).

In 2009, 15.1 percent of prevalent dialysis patients had one or more transfusion events. By unit affiliation, the percentage ranges from 12.7 in units owned by DCI to 17 in independently owned and hospital-based units. Figure 10.9; see page 391 for analytical methods. Point prevalent dialysis patients, 2009.
Overall, 61 percent of prevalent dialysis patients with diabetes received four or more glycosylated hemoglobin (A1c) tests in 2008–2009. Patients in units owned by DCI were the least likely to receive four or more tests, at 47 percent. Forty-four percent of diabetic patients receive fewer than two lipid tests annually; this reaches 62 percent in DCI units. And across unit affiliations, 57.3 percent of diabetic patients did not receive a diabetic eye examination during 2008–2009. » Figures 10.10–12; see page 391 for analytical methods. Point prevalent dialysis patients with diabetes, age 18–75, 2008–2009.

In the prevalent dialysis population, influenza vaccination rates reached 69 percent overall in 2009, and were highest in units owned by DaVita and DCI, at 80 and 72 percent, respectively. With an overall rate of 30 percent, pneumococcal pneumonia vaccination rates in 2008–2009 ranged from 20 in hospital-based units to 36 in units owned by DaVita. And 28 percent of prevalent dialysis patients received a hepatitis B vaccination in 2009, with a range from 23 in DCI units to 29–30 in units owned by Fresenius and DaVita. » Figures 10.13–15; see page 391 for analytical methods. Point prevalent dialysis patients, 2009.
Per person per year (PPPY) costs for dialysis rose just 1.5 percent in 2009, to $17,851; growth has slowed from 7.5 percent in 2006. PPPY costs for IV iron rose nearly 10 percent, to $789, while costs for erythropoiesis stimulating agents (ESAs) and for other injectables each rose 7.6 percent, to $6,175 and $224, respectively.

By unit affiliation, PPPY dialysis costs in 2009 ranged from $17,016 in hospital-based units to $18,717 in the small dialysis organizations (SDOs), while ESA costs were lowest in hospital-based units, at $5,296, and highest in units owned by Fresenius, at $6,625. DaVita units had the highest PPPY costs for both IV iron and IV vitamin D hormone, at $876 and $1,671, respectively. Laboratory costs ranged from $1,382 in DCI units to more than $1,900 in independent units and those owned by SDOs. » Figures 10.16–17; see page 391 for analytical methods. Period prevalent dialysis patients (10.16); period prevalent dialysis patients, 2009 (10.17).
For 2009, standardized hospitalization ratios (SHRs) are almost equal in small and large dialysis organizations (SDOs and LDOs), as are standardized mortality ratios (SMRs). Independent facilities have the highest SHR, and hospital-based facilities the highest SMR. By unit affiliation among the LDOs, DCI continues to have the lowest ratios for both hospitalization and mortality.

Within the SDOs, three U.S. Census Divisions — East North Central, Middle Atlantic, and New England — have statistically significant higher SHRs; the Mountain and Pacific divisions have statistically significant lower ones. A mortality ratio less than one and statistically significant occurs only in the Pacific division. Among hospital-based units, the Mountain, Pacific, and West North Central divisions have lower SHRs, while the East South Central, South Atlantic, and West South Central divisions each have higher SHRs and SMRs. **Figures 10.18–21; see page 391 for analytical methods. January 1 point prevalent hemodialysis patients, 2009, with Medicare as primary payor (SHRs); January 1 point prevalent hemodialysis patients, 2009 (SMRs). SHRs & SMRs are calculated based on national hospitalization & death rates. Adj: age/ gender/race/dialysis vintage.**
In units owned by Fresenius and DaVita, white patients have statistically significant higher SHRs, while African American patients have statistically significant lower SHR in Fresenius units, and lower SMRs in DaVita units. In hospital-based units, SHRs are lower than one and statistically significant for whites, but higher than one for African Americans.

Among hospital-based dialysis units in the Middle Atlantic and South Atlantic divisions, white patients have a statistically significant higher SHR, as do African Americans in the East North Central, East South Central, Middle Atlantic, New England, South Atlantic, and West South Central divisions. In the Mountain and Pacific divisions, the SHR is lower than one for both whites and African Americans. SMRs greater than one and statistically significant are reported for both white and African American patients in the East South Central, South Atlantic, and West South Central divisions. ▶ Figures 10.22–25: see page 391 for analytical methods. January 1 point prevalent hemodialysis patients, 2009, with Medicare as primary payor (SHRs); January 1 point prevalent hemodialysis patients, 2009 (SMRs). SHR & SMR are calculated based on national hospitalization & death rates. Adj: age/ gender/race/dialysis vintage.
Patient distribution, by unit affiliation, 2009

LARGE DIALYSIS ORGS. 63.4% > SMALL DIALYSIS ORGS. 11.6% > HOSPITAL-BASED 10% > INDEPENDENT 15% (FIG 10.1)

EPO-treated prevalent patients with hemoglobin of ≥12 g/dl, 2009

> FRESENIUS 18% > DAVITA 20% > DCI 25% > SDO 20% > INDEPENDENT 19% > HOSPITAL-BASED 20% (FIG 10.5)

Diabetic dialysis patients with 4+ AIC tests annually, 2008–2009

> FRESENIUS 63% > DAVITA 65% > DCI 47% > SDO 65% > INDEPENDENT 64% > HOSPITAL-BASED 42% (FIG 10.10)

Diabetic dialysis patients with 2+ lipid tests annually, 2008–2009

> FRESENIUS 57% > DAVITA 52% > DCI 38% > SDO 64% > INDEPENDENT 66% > HOSPITAL-BASED 48% (FIG 10.11)

Influenza vaccination rates, 2009

69%

> FRESENIUS 66% > DAVITA 80% > DCI 72% > SDO 66% > INDEPENDENT 63% > HOSPITAL-BASED 61% (FIG 10.13)

Pneumococcal pneumonia vaccination rates, 2008–2009

30%

> FRESENIUS 32% > DAVITA 36% > DCI 30% > SDO 27% > INDEPENDENT 24% > HOSPITAL-BASED 20% (FIG 10.14)

Hepatitis B vaccination rates, 2009

28%

> FRESENIUS 30% > DAVITA 29% > DCI 23% > SDO 27% > INDEPENDENT 28% > HOSPITAL-BASED 24% (FIG 10.13)

Per person per year costs for dialysis, 2009

$17,851

> FRESENIUS $17,602 > DAVITA $18,227 > DCI $17,705 > SDO $18,717 > INDEPENDENT $18,024 > HOSPITAL-BASED $17,016 (FIG 10.17)

Per person per year costs for erythropoietin stimulating agents, 2009

$6,175

> FRESENIUS $6,625 > DAVITA $6,470 > DCI $6,330 > SDO $5,782 > INDEPENDENT $5,635 > HOSPITAL-BASED $5,296 (FIG 10.17)

Per person per year costs for IV iron, 2009

$789

> FRESENIUS $842 > DAVITA $876 > DCI $818 > SDO $770 > INDEPENDENT $684 > HOSPITAL-BASED $598 (FIG 10.17)

Per person per year costs for IV vitamin D hormone, 2009

$1,361

> FRESENIUS $1,385 > DAVITA $1,671 > DCI $1,268 > SDO $1,364 > INDEPENDENT $1,149 > HOSPITAL-BASED $939 (FIG 10.17)

All-cause standardized hospitalization and mortality ratios

STANDARDIZED HOSPITALIZATION RATIOS > ALL 1.00 > LDOS 0.99 > SDO 0.99 > INDEPENDENT 1.02 > HOSPITAL-BASED 1.01 (FIG 10.18)

STANDARDIZED MORTALITY RATIOS > ALL 1.00 > LDOS 0.99 > SDO 0.98 > INDEPENDENT 1.00 > HOSPITAL-BASED 1.08 (FIG 10.18)

All-cause standardized hospitalization and mortality ratios in large dialysis organizations, 2009

STANDARDIZED HOSPITALIZATION RATIOS

> ALL 0.99 > FRESENIUS 0.99 > DAVITA 1.01 > DCI 0.91 (FIG 10.19)

STANDARDIZED MORTALITY RATIOS

> ALL 0.99 > FRESENIUS 1.00 > DAVITA 0.97 > DCI 0.96 (FIG 10.19)