Précis: an introduction to end-stage renal disease in the U.S.
This year the USRDS presents new information on the first full year of the new dialysis “bundled” Prospective Payment System, which started in January, 2011. We assess changes in the use of peritoneal dialysis, home hemodialysis, and in-center dialysis (Figures 1.18 and 1.20) as their cost structures are different for providers (2012 ADR, Figures 11.20–11.25). We also show changes in the use of injectable medications as reported by others, and illustrate that hospitalization and mortality rates continue to decline during the first year of the new dialysis payment system. We report as well on new methods to assess hospitalizations, present comprehensive data on various types of heart failure, and update analyses of prescription medication use.

In 2011, the number of patients receiving ESRD treatment reached 615,899 — a new high. The number of patients starting ESRD therapy (with dialysis or a preemptive kidney transplant) fell to 115,643, a one-year decline of 1.5 percent, yielding an adjusted rate of 357 per million population, while the number of new patients starting dialysis fell for the first time in three decades, to 110,580, and the number returning from a failed kidney transplant fell to pre-2009 levels. The prevalent dialysis population (including other peritoneal and unknown dialysis) reached 430,273 on December 31; the one-year growth of 3.2 percent was the lowest in two decades. And the number of kidney transplants reached 17,671, just 107 less than in 2010, while the prevalent transplant population reached 185,626 — with a 3.7 percent one-year increase, the slowest growth in two decades. The transplant wait list grew to 90,479.

The overall adjusted rate of incident ESRD cases fell from 371 in 2010 to 357 in 2011, a level last seen prior to 1999. Clear racial differences persist, with minority populations younger than 50 showing a continued rise in ESRD due to diabetes. Interestingly, however, minority populations older than 50 have seen greater declines in diabetic ESRD than those occurring among whites.

Patients who see a nephrologist for more than 12 months before initiation are more likely to use a fistula at the first outpatient dialysis than those with no nephrology care (32 versus 3.8 percent). Nephrologists are central to discussions about treatment options, and greater pre-ESRD referral would help ensure increased use of fistulas, which are associated with the lowest rates of adverse events. Interestingly, despite the CKD education benefit implemented in June, 2010, with its option for up to six education sessions for patients with Stage 4 CKD, but overall the benefit is used by less than 2 percent of patients.

In new analyses we compare hospitalization rates using only the principal diagnosis code to those based on both principal and secondary codes. We had identified coding drift in analyses of hospitalizations due to infection, with use of DRG codes for sepsis syndrome — which carry a higher payment — rising over time. We found that the use of codes for bacteremia/sepsis was climbing in the ESRD and general populations while the use of other infection codes was falling, which suggested the potential for misclassification. Rates of hospitalizations for a certain type of infection (using just the principal diagnosis code) compared to rates with that infection (using both principal and secondary codes) show marked differences by modality and type of infection. Bacteremia/sepsis in hemodialysis patients, for example, and peritonitis in peritoneal dialysis patients, are under-reported when only principal diagnosis codes are considered; rates
using both types of codes are considerably higher. More investigation is needed to determine the strengths and weakness of these findings.

Data on cardiovascular disease in the ESRD population show that sudden death accounts for one-fourth of all deaths, and illustrate the increasing use of prescription drugs to treat heart failure, AMI, and atrial fibrillation.

This year, to highlight the early hazards for incident patients, we have changed all mortality rate calculations to start at day one of ESRD versus the traditionally used day 90. Data show the impact of this change, with higher first-year mortality rates from day one in hemodialysis patients, but similar rates in the peritoneal dialysis population. Outcomes for these latter patients merit increased attention, as incentives to use peritoneal dialysis have changed under the new bundled payment system.

Updated data on the Medicare Part D prescription drug benefit, which started in 2006, show that 77 and 64 percent of hemodialysis and peritoneal dialysis patients were enrolled in Part D in 2011, compared to 56–60 percent of general Medicare and transplant patients.

In 2011 the kidney transplant wait list for active and inactive patients continued to grow, reaching 90,474, and 17,671 transplants were performed. Acute rejection episodes within the first year have reached a low of 10 percent, while graft outcomes continue to improve.

In the pediatric population, hospitalizations for infection have increased, with the youngest patients being the most vulnerable. Rates are greater among dialysis patients younger than five, and peritoneal dialysis is associated with higher rates than hemodialysis.

The Quality of Life/Rehabilitation and Nutrition Special Studies Centers present data on frailty from the ACTIVE/ADIPose study. Almost 70 percent of the studied population was classified as pre-frail or frail, with frailty associated with injuries and fractures. These findings have important implications to the care of dialysis patients, who have considerable comorbidity, and in whom secondary hyperthyroidism and bone disease adds to the potential for adverse complications.

Dialysis providers continue to consolidate, with Fresenius Medical Care announcing the purchase of additional units in July, 2011; the company thus maintains its position as the largest provider of dialysis care in the U.S. Overall, 92.2 percent of dialysis providers opted into the new bundled Prospective Payment System for dialysis, or "bundle."

Comparing data from July, 2010, and July, 2012, and looking at units opting into the bundle, the mean monthly EPO dose (units) declined 39 percent, while IV iron and IV vitamin D dosing declined 21 and 15.6 percent. Average hemoglobin levels decreased from 11.3 g/dl in to 10.6 in, while the percentage of patients with at least one transfusion event rose from 2.5 to 3.1.

dci continues to have the lowest adjusted standardized hospitalization and mortality ratios among the large providers, while, among the smaller providers, hospital-based units have the highest standardized mortality ratios. DaVita again this year had mortality ratios similar to those of dci.

We conclude the Précis with data on the costs of ESRD patient care. Costs per person per year (PPPY) remain highest for hemodialysis patients, at $87,945, compared to $71,630 and $32,922 for peritoneal dialysis and transplant patients. The jump of $4,400 in PPPY expenditures for peritoneal dialysis patients merits further investigation.

- Figure p.1; see page 428 for analytical methods. Period prevalent general (fee-for-service) Medicare patients.

### General Medicare: population, 2001
(n = 30,648,445; mean age 69.7)

- CKD 4.8%
- DM 19.8%
- CHF 14.0%
- ESRD 1.1%
- None 69.8%

### General Medicare: costs, 2001
($183 billion)

- CKD 15.7%
- DM 35.2%
- CHF 40.9%
- ESRD 7.2%
- None 39.1%

### General Medicare: population, 2011
(n = 31,699,027; mean age 69.1)

- CKD 12.7%
- DM 27.5%
- CHF 13.2%
- ESRD 1.4%
- None 61.2%

### General Medicare: costs, 2011
($355 billion)

- CKD 28.9%
- DM 43.8%
- CHF 36.5%
- ESRD 7.2%
- None 34.0%
Summary statistics on reported ESRD therapy in the United States, by age, race, ethnicity, gender, & primary diagnosis, 2011

## Incidence

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<th>Age Group</th>
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<th>Adjusted Rate per 100,000</th>
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## December 31 point prevalence

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<th>(p&lt;0.01)</th>
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<th>(p&lt;0.01)</th>
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## Medicare & non-Medicare spending

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<td>Medicaid</td>
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<td>Peritoneal dialysis</td>
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<tr>
<td>Total</td>
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## Footnotes

- *Values for cells with too few patients are suppressed. **Zero patients in this cell.
In 2011, 115,643 new dialysis and transplant patients initiated ESRD therapy, for an adjusted rate per million population of 357. On December 31, 2011, there were 615,899 patients receiving treatment, for an adjusted rate of 1,901 per million population. More than 430,000 of these patients were being treated with dialysis, while 185,626 had a functioning graft; 92,221 ESRD patients died during the year. A total of 17,671 transplants were performed during 2011, including 5,772 from living donors. Slightly more than 34,000 patients were added to the transplant wait lists (kidney and kidney/pancreas), 90,479 were on the kidney and kidney/pancreas wait lists at the end of 2011, and the median time on the list (for pediatric and adult patients combined) was 1.8 years.

With Medicare spending for ESRD at $34.4 billion, and non-Medicare spending at $14.9 billion, total ESRD costs in 2011 reached $49.3 billion. Medicare costs per person per year were more than $75,000 overall, ranging from $32,922 for transplant patients to $87,945 for those receiving hemodialysis therapy. *Table p.4; see page 428 for analytical methods.* Dialysis & transplant patients, 2011.

The number of new dialysis patients fell 1.9 percent in 2011, to reach 110,580 patients. Close to 5,500 patients with graft failure returned to dialysis from transplant, a number similar to that of the previous year. The number of patients restarting dialysis increased 4 percent, to 3,894. Overall, the CMS Annual Facility Survey showed 119,970 patients starting or restarting dialysis in 2011, down 1.7 percent from 2010. *Figure p.2; see page 428 for analytical methods. CMS Annual Facility Survey.*

The size of the prevalent dialysis population increased 3.2 percent in 2011, reaching 430,273. The size of the transplant population rose 3.7 percent, to 185,626 patients, while the number of incident patients fell 1.5 percent, to 115,643. *Figure p.3; see page 428 for analytical methods. CMS Annual Facility Survey.*

Of the 8,208 incident patients who received renal replacement therapy at home in 2011, 9.4 percent were treated with hemodialysis, 64.7 percent were treated with CAPD, and 26 percent used CCPD. *Figure 1.18; see page 430 for analytical methods. Incident dialysis patients.*
In 2011, the population initiating on peritoneal dialysis grew for the third year in a row; it now accounts for 6.6 percent of patients with a known dialysis modality. The number of total incident dialysis patients fell 1.5 percent, to 112,788, while 2,855 patients received a preemptive transplant as their first ESRD modality; a total of 115,643 patients thus began ESRD therapy in 2011. • Figure 1.1; see page 430 for analytical methods. Incident & December 31 point prevalent ESRD patients.

After a 1.9 percent decrease in 2010, the incident rate of ESRD (adjusted for age, gender, and race) continued to decline, falling 3.8 percent in 2011 to 357 per million population. Since 2000, changes in the adjusted rate have shown little variation, but the 2011 adjusted rate is the lowest since 1998. Ethnicity was added to the Medical Evidence form in 1995. When adjusted for Hispanic ethnicity, rates differ little from those adjusted for age, gender, and race alone. In 2005, for example, the incident rate including ethnicity was 0.5 percent greater, and in 2011 it was 0.2 percent less, at 356.4 per million population compared to 357.1. • Figure 1.2; see page 430 for analytical methods. Incident ESRD patients. Adj: age/gender/race; ref: 2010 ESRD patients.

The adjusted rate of prevalent cases of end-stage renal disease rose 1.3 percent in 2011 — slightly lower than the growth of 1.8 percent in 2010 — to 1,901 per million population. This rate is 26 percent higher than that seen in 2000. Until 2011, the annual rate of increase had remained between 1.7 and 2.2 percent since 2004. • Figure 1.10; see page 430 for analytical methods. December 31 point prevalent ESRD patients. Adj: age/gender/race; ref: 2010 ESRD patients.

By race, rates for blacks/African Americans and Native Americans in 2011 were 940 and 453 per million population, respectively — 3.4 and 1.6 times greater than the rate of 280 found among whites. After rising in the middle of the decade, the rates for both whites and Asians are now near the levels seen in 2000, while rates for blacks/African Americans and Native Americans are now 10.2 and 36 percent lower.

Rates of prevalent ESRD by race remain greatest in the black/African American and Native American populations, at 5,584 and 2,701 per million population in 2011, compared to 1,396 and 2,265 among whites and Asians. The rate among Hispanics reached 2,818 in 2011. • Figures 1.5 & 1.13; see page 430 for analytical methods. Incident ESRD patients (1.5). December 31 point prevalent ESRD patients (1.13). Adj: age/gender. Ref: 2010 ESRD patients.
Both the rates of incident ESRD caused by diabetes and their growth over time continue to vary widely by age and race/ethnicity. Among whites age 30–39, for example, the rate (adjusted for gender) has increased just 3.5 percent since 2000, reaching 37 per million population in 2011. For blacks/African Americans of the same age, in contrast, the rate has increased 72 percent since 2000, to reach 136. Among blacks/African Americans age 40–49, the rate of incident ESRD has increased just 8.2 percent since 2000; among Native Americans of the same age, the rate is 11 percent lower than in 2000 (though rising after reaching a low in 2007). Among both populations, however, the current rates of 309 and 321 per million population, respectively, remain 3.5–3.6 times greater than among their white counterparts. *Figures 1.3, 1.11, & 1.8; see page 430 for analytical methods. Incident (1.3) & December 31 point prevalent (1.11) ESRD patients. Adj: age/gender/race/ethnicity; ref: 2010 ESRD patients. 1.8: Incident ESRD patients; rates are three-year rolling averages. Adj: gender; ref: 2010 ESRD patients.
Among hemodialysis patients who have seen a nephrologist for more than a year prior to starting ESRD therapy, 41 percent initiate treatment using a catheter only; patients with this amount of care have the greatest likelihood at initiation of having an arteriovenous fistula (AV) or maturing fistula, at 31.9 and 20.8 percent, respectively. Patients with no pre-ESRD nephrology care most frequently start treatment with a catheter, at 81 percent, while only 16.3 percent initiate with either a mature or maturing AV fistula or graft. • Figure 1.22; see page 430 for analytical methods. Incident hemodialysis patients, 2011.

Mean hemoglobin levels at initiation have fallen from their peak in 2006 (10.24 g/dl), reaching 9.63 g/dl overall at the end of 2011, and they no longer vary between patients who receive pre-ESRD ESA treatment and those who do not. The number of patients receiving ESA treatment prior to initiation has changed 34 percent in 2002–2004 to 18–20 percent during 2011. • Figure 1.23; see page 430 for analytical methods. Incident ESRD patients.

On January 1, 2010, CMS added Kidney Disease Patient Education System services as a benefit to Medicare beneficiaries diagnosed with Stage 4 CKD. The service provides patients with information on comorbidity, treatment in the prevention of uremia, and choices for renal replacement therapy should the need arise. The education benefit can be individualized giving each patient the opportunity to actively participate in their treatment choices. Pre-ESRD patients (those who initiate renal replacement therapy) are more likely to utilize the education benefit than those with Stage 4 CKD, but overall, the benefit is used by less than 2 percent of patients. • Figure 7.26; see page 148 for analytical methods. General Medicare patients with CKD age 65 & older, & pre-ESRD patients age 67 or older at initiation of ESRD.
At the end of 2011, 58 percent of prevalent hemodialysis patients had a mean monthly hemoglobin less than 11 g/dl, while 31 percent had hemoglobins that ranged from 11 g/dl to less than 12 g/dl. The mean EPO dose per week fell each month within the year, ending at 12,460 in the month of December, more than 3,600 units less than the average dose at the end of 2010; the mean hemoglobin at the end of 2011 was 10.7 g/dl.

When compared to 2007, incident hemodialysis patients starting dialysis in 2011 did so with lower hemoglobins one month post-initiation, at 10.7 and 10.1 g/dl, respectively. In 2011, the mean hemoglobin level six months after initiation was slightly below 10.9 g/dl.

The mean EPO dose per week at six months after initiation was 15,213 units in 2011, compared to 20,506 units in 2007. Between 2010 and 2011, the proportion of incident hemodialysis patients receiving IV iron in each of the first six months of dialysis showed a relative increase of 12 percentage points, to 52.1 percent.

The percentage of hemodialysis patients receiving a transfusion has increased little since 2010, and in June of 2011 was slightly higher in whites compared to blacks/African Americans, at 3.5 and 3.1 percent, respectively. When compared to 2007, the proportion of incident hemodialysis patients receiving IV iron in each of the first six months of dialysis showed a relative increase of 12 percentage points, to 52.1 percent.

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For Figure 2.7, each month includes patients with a claim for hemodialysis. * Figures 2.4–7; see page 431 for analytical methods.
In 2011, admissions per patient year for hemodialysis patients were 1.84 nearly identical to those in 1993. Rates for peritoneal dialysis and transplant patients, in contrast, have fallen 14.0 and 15.7 percent. Hospital days per patient year have fallen to 11.7 for both hemodialysis and peritoneal dialysis patients, and to 5.7 for those with a transplant. *Figure 3.2; see page 433 for analytical methods. Period prevalent ESRD patients. Adj: age/gender/race/primary diagnosis; ref: ESRD patients, 2010.*

Since 1993, adjusted infection hospital days per patient year have increased 19.2 percent for hemodialysis patients, but have decreased 19.4 and 25.2 percent, respectively, for patients on peritoneal dialysis or with a transplant. Among patients with a cardiovascular hospitalization, in contrast, hospital days have fallen 36.7 overall for dialysis patients and 57.6 percent in those with a transplant.

Adjusted infection and cardiovascular hospital days are higher for patients on dialysis than for those with a transplant. For infection hospital admissions, for example, hospital days per patient year in 2011 were 4.0 and 4.5, respectively, for hemodialysis and peritoneal dialysis patients, compared to 1.7 for those with a transplant. And among patients with a cardiovascular admission, hospital days were 2.5 per patient year for hemodialysis and peritoneal patients compared to 0.7 for those with a transplant. *Figure 3.3; see page 433 for analytical methods. Period prevalent ESRD patients. Adj: age/gender/race/primary diagnosis; ref: ESRD patients, 2010.*

Rates of hospitalization for infection in the hemodialysis population have increased 43 percent since 1993—in contrast, for example, to a 57 percent decrease in hospitalizations for vascular access procedures. Infection hospitalization rates in peritoneal patients are only 2 percent lower than 1993 rates but decreases in hospitalizations due to the dialysis access are more encouraging and have fallen 28 percent since 1993. *Figure 3.1; see page 433 for analytical methods. Period prevalent ESRD patients; adjusted for age/gender/race/primary diagnosis; ref: ESRD patients, 2010.*
For infection hospitalizations, the adjusted hospital admission rate for hemodialysis patients in 2011 is 903 per 1,000 patient years when both principal and secondary inpatient diagnosis codes are used; when only principal codes are used, the rate falls to 462. Among patients on peritoneal dialysis or with a transplant, 2011 rates using both types of codes are 935 and 505, respectively, while rates using only principal diagnosis codes are 551 and 233, respectively. Overall, infectious hospital admission rates did not improve across years with either method.

Rates in 2011 for bacteremia/sepsis admissions in hemodialysis, peritoneal dialysis, and transplant patients are 282, 201, and 109 per 1,000 patient years, respectively, when using both types of diagnosis codes, and 123, 82, and 57 when using only principal diagnosis codes.

Among hemodialysis and peritoneal dialysis patients, 2011 dialysis-related infection rates using both code types are 118 and 354, respectively, in contrast to rates of 88 and 81 when using principal diagnosis codes alone. Rates of admission with peritonitis in peritoneal dialysis patients, using both code types, are 2–4 times higher than rates of admission with vascular access infection in hemodialysis patients. • Figures 3.4–6; see page 433 for analytical methods. Period prevalent ESRD patients (3.4–5); period prevalent dialysis patients (3.6). Adj: age/gender/race/primary diagnosis; ref: ESRD patients, 2010. Admission rates with the stated condition using both principal & secondary diagnosis codes could be elevated in 2010 & 2011 due to availability of additional inpatient diagnosis code fields beginning in 2010.

**Definitions**

1. Admission with the condition: uses principal & secondary inpatient diagnosis codes during hospital stay
2. Admission for the condition: uses principal diagnosis codes only
During 2009–2011, the overall mortality rate was considerably higher among incident patients than in the prevalent population, at 298 compared to 194 deaths per 1,000 patient years.

In both the incident and prevalent populations, cardiac death due to arrhythmic mechanisms continues to be the single largest cause of attributable mortality. Reflecting the unique nature of dialysis therapy, withdrawal is the second most common cause; this is somewhat misleading, however, as the occurrence of withdrawal is likely a surrogate for other underlying conditions such as advanced dementia, wasting, failure to thrive, etc. *Figure 4.1*; see page 440 for analytical methods. *Incident & prevalent dialysis patients, 2009–2011.*
Data on practice patterns in the medical treatment of cardiovascular disease in prevalent 2011 ESRD patients show a widespread use of beta blocker therapy. Presumably, most patients identified as receiving beta blockers and ACEIs/ARBs for “no cardiac event” were in reality receiving these agents for anti-hypertensive therapy. More than three quarters of hemodialysis patients, the most recent peritoneal dialysis, received statin therapy, as did two-thirds of transplantation in statin use. Even among patients with “no cardiac event,” there has been no apparent reduction in statin use. Reflecting this clinical uncertainty, warfarin therapy was identified in only 38 percent of 2011 hemodialysis patients with atrial fibrillation, and in 43 percent of their peritoneal dialysis patients counterparts. And despite the lack of safety data on its use in dialysis patients, amiodarone is received by 18–19 percent of dialysis patients with atrial fibrillation.

In 2010, the first of the “novel” oral anticoagulants, dabigatran, was approved for use in the U.S. It is not approved for use in dialysis patients. Based on Part D data, a few dialysis patients have already been prescribed this agent. This trend needs to be followed closely, as there are significant safety concerns related to hemorrhagic risk. The use of Part D Medicare data to examine medication use in dialysis patients may provide a means of performing pharmacovigilance—including the tracking of off-label medication use—in this special, high-risk population. Table 4.C see page 437 for analytical methods. January 1 point prevalent patients with Medicare Parts A, B, & D enrollment & with a cardiovascular diagnosis or procedure in 2011.
This year we have changed the mortality analyses in the atlas and reference tables to start from day one of registered ESRD, eliminating missed deaths from the first 90 days. Figure 5.1 contrasts death rates from day one and day 90, showing that, between 1997 and 2011, rates from day one are 17–20 percent greater for hemodialysis patients than those tracked from day 90.

Trends in mortality rates by vintage are unchanged, since the issue of day one versus day 90 only affects patients in the first year. Between 1993 and 2003 there was little improvement in first-year death rates in the ESRD population. Between 2003 and 2010, however, rates fell more than 16 percent, while second-year death rates declined 21 percent between 2002 and 2009. • Figure 5.1; see page 439 for analytical methods.

Figure 5.4 shows adjusted all-cause mortality rates from day one of hemodialysis and from day 90. Rates are somewhat different between the two cohorts. Using data from day 1, for example, for years 2000 and after, the death rate among patients with a vintage of 2–<5 years is lower than the rate for those with a vintage of less than two years, a phenomenon less evident when looking at data from day 90.

Another difference between the two cohorts relates to patients with a vintage of less than two years. Rates calculated from day one are 10.8 percent higher than those calculated using data from day 90, at 207.3 versus 187.1 per 1,000 patient years in 2011. • Figure 5.4; see page 439 for analytical methods.

Through the 1980s, patients newer to dialysis had higher mortality rates than those on treatment for five years or more. In the mid-1990s, however, this trend began to change.

Figure 5.4 shows adjusted all-cause mortality rates from day one of hemodialysis and from day 90. Rates are somewhat different between the two cohorts. Using data from day 1, for example, for years 2000 and after, the death rate among patients with a vintage of 2–<5 years is lower than the rate for those with a vintage of less than two years, a phenomenon less evident when looking at data from day 90.

Another difference between the two cohorts relates to patients with a vintage of less than two years. Rates calculated from day one are 10.8 percent higher than those calculated using data from day 90, at 207.3 versus 187.1 per 1,000 patient years in 2011. • Figure 5.4; see page 439 for analytical methods.
The new dialysis Prospective Payment System, or “bundle,” took effect in January, 2011. Antibiotics administered during hemodialysis for a vascular access infection or prescribed for peritonitis treatment in a peritoneal dialysis patient are considered ESRD-related, and are now covered in the bundled payment. Dialysis facilities are, however, required to document these medications on the Medicare claims form. Here we examine use of oral and intravenous (iv) antibiotics before and after implementation of the bundle. After implementation, iv antibiotics were covered under Part B (through the bundle or separate reimbursement); the proportion of patients receiving any iv antibiotics under Part D was less than 1 percent.

Overall, the proportion of patients receiving at least one iv antibiotic decreased slightly between 2010 and 2011. Vancomycin was the most used antibiotic, and daptomycin the least. Vancomycin use fell from 21.2 and 0.8 percent under Parts B and D, respectively, in 2010 to 20.7 and 0.6 percent in 2011. Cefazolin use remained constant pre- and post-dialysis bundle, and use of other antibiotics was more limited.

In 2011, DCI units had the highest percentage of patients using vancomycin, cephalosporins (including cefazolin), and aminoglycosides.

The percentage of patients receiving quinolones fell from 22.4 to 18.8 percent pre- to post-bundle, while macrolide and penicillin use increased slightly. There was a slight decrease in the percentage of patients receiving oral cephalosporins in Fresenius, DaVita and DCI units, while the numbers rose slightly in the SDOs and in independent and hospital-based units. **Figures 6.14–16; see page 441 for analytical methods.** **Point prevalent Medicare enrollees alive on January 1.**
In 2011, 17,671 kidney transplants were performed in the U.S.—111 fewer than in 2010. There were 503 fewer living donor transplants, an 8.0 percent decrease, while deceased donor transplants increased 3.4 percent. The number of kidney transplants has remained stable since 2005, paralleling a leveling off of the ESRD incidence rate. And the number of patients alive with a functioning kidney transplant continues to climb, reaching over 181,000 in 2011. *Figure 7.1; see page 441 for analytical methods.*

Unadjusted transplant rates: limited to ESRD patients age 20 & older, thus yielding a computed incident rate higher than the overall rate presented elsewhere in the Annual Data Report. Wait list counts: all patients listed for a kidney or kidney-pancreas transplant on December 31 of each year. Wait time: all patients entering wait list in the given year. Transplant counts: all patients known to the USRDS. Functioning transplant: annual status of all patients who received a kidney or kidney-pancreas transplant, regardless of transplant date.

The adjusted deceased donor transplant rate has increased 61 percent since 2000 for patients age 65 and older, while falling 46 percent for those age 18–34. By race, the rate is down 33 percent among whites, while rising 9.1 and 12 percent for blacks/African Americans and Asians, respectively. *Figure 7.13; see page 442 for analytical methods.*

Since the early 2000s, rates of living donor transplants have fallen for many patient groups. As with deceased donor transplants, rates by race are now greatest in the Asian population, reaching 2.1 per 100 dialysis patient years in 2011—24 percent higher than in 2000. *Figure 7.15; see page 442 for analytical methods.*
Among those transplanted in 2008, metoprolol tartrate was the most frequently used medication in the first three years post-transplant. Valganciclovir hydrochloride was the most costly medication in the first two years post-transplant, and insulin the most costly in year three. • Tables 7a-b; see page 443 for analytical methods. Patients enrolled in Medicare Part D & transplanted in 2008. Costs are estimated Medicare payment, defined as the sum of plan covered payment amount & low income subsidy amount. "Year 1" is the period from transplant to one year later. Years 2 & 3 are similarly defined.
In 2011, 696 children initiated ESRD treatment on hemodialysis, 382 were placed on peritoneal dialysis and 280 received a transplant. Prevalent counts were 1,508, 911, and 5,469, respectively, for hemodialysis, peritoneal dialysis, and transplant. • Figure 8.11; see page 444 for analytical methods. Incident & prevalent ESRD patients age 0–19, 2011.

Between 2001–2005 and 2006–2010, one-year adjusted all-cause hospitalization rates increased 21 and 19 percent, in patients age 0–9 and 15–19, while falling 1.4 percent in patients age 10–14. The rate rose 11 percent for hemodialysis patients and 24 percent for those treated with peritoneal dialysis, while increasing just 1.5 percent for patients with a transplant. • Figure 8.7; see page 444 for analytical methods. Incident ESRD pts age 0–19, 2001–2010. Adj: gender/race/Hispanic ethnicity/primary diagnosis. Ref: incident ESRD pts age 0–19, 2009–2010.

The one-year adjusted all-cause mortality rate in children age 0–9 was 93 per 1,000 patient years in 2006–2010, more than seven times higher than the rate in patients age 10–14, nearly four times higher than for patients age 15–19, and 20 percent higher than in 2001–2005. The rate for children on hemodialysis was 60.4, compared to 45 and 10.4 for those on peritoneal dialysis or with a transplant. • Figure 8.10; see page 444 for analytical methods. Incident dialysis & transplant pts defined at the onset of dialysis or the day of transplant without the 60-day rule; followed to December 31, 2011. Adj: age/gender/race/Hispanic ethnicity/primary diagnosis. Ref: incident ESRD patients age 0–19, 2009–2010.
A prospective, multi-center special data collection study coordinated by the USRDS Special Studies Centers, *ACTIVE/ADIPOSE is A Cohort Study to Investigate the Value of Exercise in ESRD* Analyses Designed to Investigate the Paradox of Obesity and Survival in ESRD. Patients were classified as non-frail (i.e., positive for no frailty indicators), frail (i.e., positive for three or more indicators), and pre-frail (i.e., positive for one or two indicators).

The odds of having fallen were 3 times greater for individuals classified as frail, and 1.6 times greater for individuals classified as pre-frail. Fall-related fractures were sustained by 11.2 percent of patients reporting a fall. Proportional odds models showed that being classified as frail or pre-frail increased the odds for having a fall complicated by a fracture, compared with having a fall without a fracture or having no fall. • Figures 9.1, 9.3, & 9.7–8; see Chapter Nine for analytical methods & patient populations.

Figure 9.10 shows intracellular water (ICW) per kg body mass and percent fat mass among frail and non-frail men and women in the *ACTIVE/ADIPOSE* study. Men and women who were frail had significantly lower ICW per kg, a marker of muscle mass. Conversely, frail men and women had higher percent fat mass, suggesting that excess adiposity is more common among frail individuals.

Hemoglobin was slightly lower among frail patients, but there was no significant association between frailty and bone and mineral parameters. Frail participants had slightly higher predialysis serum bicarbonate than non-frail individuals, which could indicate lower dietary acid intake related to low protein intake. • Figure 9.10 & Table 9.d; see Chapter Nine for analytical methods & patient populations.
At the end of 2011, 132,744 prevalent patients were being treated by Fresenius in 1,829 units; 126,763 were receiving care in one of DaVita’s 1,747 units; and 13,195 patients were being treated by Dialysis Clinic Inc., with 215 units, the latter showing little change from 2010. These three providers manage the majority of the 6,009 dialysis units across the United States. Small dialysis organizations (SDOs), comprising 20–199 units, treated 49,102 patients in 665 units, while independent and hospital-based providers treated 56,339 and 36,034 patients in 788 and 765 units, respectively. In the independent and hospital-based units, numbers of patients and units continue to decline. • Figure 10.1; see page 444 for analytical methods. CMS Annual Facility Survey, 2011.

Between July, 2010 and July, 2012, the overall percentage of patients receiving EPO fell from 86 to 80. In units opting into the bundle, EPO doses fell 39 percent overall, and 30–42 percent in large chain affiliated units, SDOs, independent units, and units that are hospital-based. IV iron total monthly doses fell 21 percent overall, and 34.5 percent in DaVita units, but only 1.5 percent in hospital-based units. Vitamin D doses declined 15.6 percent across all providers, 27 percent in DaVita units, and just 4.2 percent in units owned by Fresenius.

Average hemoglobin levels fell 6.6 percent, from 11.3 g/dl to 10.6 g/dl in July, 2012. Across providers, the range of levels fell from 11.2–11.4 to 10.5–10.8.

Overall, the percentage of patients with at least one transfusion event increased from 2.5 to 3.1 between July, 2010, and July, 2012. The largest increases occurred in units owned by DaVita and those classified as SDOs. • Figure 10.7; see page 445 for analytical methods. Period prevalent dialysis patients.
In July 2010, the percentage of dialysis patients with at least one transfusion event was 2.5% nationwide, averaging 1.9% and 3.3% percent, respectively, in the upper and lower quintiles. Patients residing in the upper Midwest, parts of Texas, the South Central U.S., and parts of New England were most likely to receive a transfusion.

The ESRD bundled Prospective Payment System (PPS) was implemented in January 2011, and appears to have directly affected the use of EPO and other injectable therapeutics (see Figure 10.7). In 2011, for example, the transfusion rate for dialysis patients was 2.9% percent nationwide and averaged 3.5% percent in the upper quintile, which included patients residing in Texas, Louisiana, and the eastern one-third of the country.

In 2012 (one year after implementation of the bundle), the likelihood of a transfusion event was far more widespread geographically, averaging 3.0% percent nationwide and 3.4% percent in the upper quintile, which included the eastern two-thirds of nation as well as parts of Arizona, Nevada, and California. • Figure 10.8; see page 445 for analytical methods. Period prevalent dialysis patients.

As of 2012, the three largest dialysis providers — Fresenius, DaVita, and DCI — had adopted the bundled payment system in virtually all of their units, while just one-half of hospital-based units, and 79 percent of independent units, had opted into the system. • Table 10.1; see page 445 for analytical methods.

Adjusted standardized hospitalization and mortality ratios (SHRs and SMRs) in small and large dialysis organizations (SDOs and LDOs) tend to be lower when compared to ratios for independent and hospital-based facilities. • Figure 10.9; see page 445 for analytical methods. All-cause standardized hospitalization & mortality ratios, by unit affiliation, 2010 & 2011.

<table>
<thead>
<tr>
<th></th>
<th>Number of facilities</th>
<th>Number opting for bundle</th>
<th>Percent of facilities</th>
<th>Percent of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All*</td>
<td>5,522</td>
<td>5,089</td>
<td>92.2%</td>
<td>91.9%</td>
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<tr>
<td>Fresenius</td>
<td>1,824</td>
<td>1,811</td>
<td>99.3%</td>
<td>99.9%</td>
</tr>
<tr>
<td>Davita</td>
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<td>1,713</td>
<td>99.1%</td>
<td>99.9%</td>
</tr>
<tr>
<td>DCI</td>
<td>213</td>
<td>212</td>
<td>99.5%</td>
<td>100.0%</td>
</tr>
<tr>
<td>SDOs</td>
<td>660</td>
<td>607</td>
<td>92.0%</td>
<td>92.6%</td>
</tr>
<tr>
<td>Independent</td>
<td>686</td>
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<tr>
<td>Hospital-based</td>
<td>410</td>
<td>205</td>
<td>50.0%</td>
<td>54.4%</td>
</tr>
</tbody>
</table>

SHRs & SMRs are calculated based on national hospitalization & death rates. Adj: age/ gender/ race/ dialysis vintage/ primary diagnosis.
In 2011, total Part D net costs were $63 billion in the general Medicare population, and reached $2.0 billion, $1.7 billion, and $323 million in the ESRD, dialysis, and transplant populations. Costs for general Medicare patients with the low income subsidy (LIS) totaled $43.6 billion, compared to $19.6 billion in non-LIS patients.

Among dialysis and transplant patients with the LIS, net per person per year Part D costs in 2011 were $8,003 and $6,459, respectively, compared to costs of $4,194 in the general Medicare population. In patients with no LIS, Part D costs were noticeably lower, at $2,302 for dialysis patients, $2,105 for transplant patients, and $1,043 in the general population.

Out-of-pocket Part D costs for patients with the LIS are a fraction of those realized by non-LIS patients, at $105 and $590, respectively, for general Medicare patients, and $119 versus $1,106 for patients with ESRD.

In 2011, total per person per year (PPPY) Part D costs for LIS patients were highest in facilities owned by DaVita and in those that operated independently, at $9,917 and $8,792, respectively. In patients with no LIS, PPPY costs were similar across all facilities, ranging from $2,218 to $2,525. • Figures 11.10–12; see page 446 for analytical methods. 11.10–11: Part D-enrolled general Medicare patients from the 5 percent sample & period prevalent dialysis & transplant patients, 2011. 11.12: Part D-enrolled dialysis patients, 2011.
Total per person per year (pppy) Part D costs in 2011 for phosphate binders, calcium acetate, sevelamer, and lanthanum were highest in units owned by DaVita, at $233, $2,244, and $418, respectively, and totaling $2,894; costs in hospital-based units, in contrast, totaled $1,665, 42 percent lower than costs incurred by DaVita facilities.

Small dialysis organizations (SDOs) and hospital-based units had the lowest pppy cinacalcet costs, at $996 and $1,048, respectively, while costs were highest in units owned by DaVita, at $1,618. **Figures 11.13–14; see page 446 for analytical methods.**

*Part D-enrolled dialysis patients, 2011.*
PRÉCIS: AN INTRODUCTION TO ESRD IN THE U.S.