

CHAPTER

6

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**Outpatient dialysis services**

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## R E C O M M E N D A T I O N

- 6** The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2012.

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

# Outpatient dialysis services

## Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2009, about 340,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 5,000 ESRD facilities. In that year, Medicare expenditures for outpatient dialysis services, including separately billable drugs administered during dialysis, were \$9.2 billion, an increase of 7 percent from 2008 spending levels.

## Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive.

**Beneficiaries' access to care**—Measures include examining the capacity and supply of providers, beneficiaries' ability to obtain care, and changes in the volume of services.

- **Capacity and supply of providers**—Dialysis facilities appear to have the capacity to meet demand. Growth in the number of dialysis treatment stations has generally kept pace with growth in the number of dialysis patients.
- **Volume of services**—Between 2008 and 2009, the number of FFS dialysis beneficiaries and dialysis treatments grew by 4 percent. Units per

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- Are Medicare payments adequate in 2011?
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treatment of erythropoietin, a drug that treats anemia and accounts for about 70 percent of dialysis drug spending, increased by 2 percent during this period.

**Quality of care**—Dialysis quality has improved over time for some measures, such as use of the recommended type of vascular access—the site on the patient’s body where blood is removed and returned during dialysis. Other measures suggest that improvements in quality are still needed. In particular, the proportion of all dialysis patients accepted for the registry on the kidney transplant waiting list remains low and mortality remains high.

**Providers’ access to capital**—Information from investment analysts suggests that access to capital for dialysis providers continues to be adequate. The number of facilities, particularly for-profit facilities, continues to increase.

**Medicare payments and providers’ costs**—In 2009, the Medicare margin for composite rate services and dialysis drugs for freestanding facilities was 3.1 percent. We project the Medicare margin for freestanding dialysis facilities will be 1.3 percent in 2011. This projection reflects the 2.5 percent update to the payment rate in 2011, the 2 percent reduction in total spending that the Medicare Improvements for Patients and Providers Act of 2008 mandated in 2011, the 3.1 percent transitional budget-neutrality adjustment, and a conservative behavioral offset to account for efficiencies in the use of drugs and laboratory tests that are anticipated under the new dialysis payment method.

Consistent with the Commission’s long-standing recommendation, a new outpatient dialysis prospective payment method began in 2011 that broadens the dialysis payment bundle and requires that CMS implement a quality incentive program beginning in 2012. As CMS phases in the new payment method, the Commission will continue its annual assessment of the adequacy of outpatient dialysis payments. In addition, the Commission will monitor key aspects of the new payment method, including paying for dialysis services in rural and other isolated areas, the availability of consumer information, and the effectiveness of the quality incentive program. ■

## Dialysis treatment choices

**D**ialysis is a treatment to replace the filtering function of the kidneys when they fail. The two types of dialysis—peritoneal dialysis and hemodialysis—remove waste products from the bloodstream differently. Peritoneal dialysis uses the lining of the abdomen as a filter to clear wastes and extra fluid and is usually performed independently in the patient’s home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient’s blood. Although hemodialysis is usually provided in

dialysis facilities, it can also be done in the patient’s home. Each dialysis method has advantages and disadvantages—no one type of dialysis is best for everyone. People choose one type of dialysis over another for many reasons, including quality of life, patients’ awareness of different treatment methods and personal preferences, and physician training and recommendation. Some patients switch from one method to another when their conditions or needs change. ■

### Background

End-stage renal disease (ESRD) is a chronic illness characterized by permanent irreversible kidney failure. ESRD patients include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and of potential patients’ suitability for transplantation, 70 percent of ESRD patients undergo dialysis per year. The text box summarizes the two types of dialysis. Patients receive additional items and services related to their dialysis treatments, including dialysis drugs to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

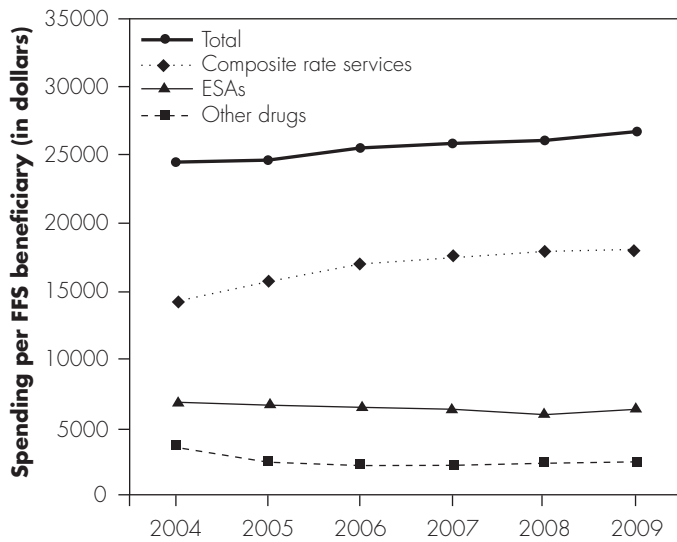
The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who are eligible for Social Security benefits, even those under age 65 years. To qualify for the ESRD program, individuals must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits under the Social Security or Railroad Retirement program, or the spouse or dependent child of an eligible beneficiary.<sup>1</sup> ESRD patients entitled to Medicare due to kidney disease alone have the same benefits as other Medicare beneficiaries.

For beneficiaries entitled to benefits due to ESRD alone, Medicare coverage does not begin until the fourth month after the start of dialysis unless the individual had a kidney transplant or began training for self-care, including those dialyzing at home. About half of new ESRD patients each year are under age 65 and thus are entitled to Medicare

because they have chronic renal failure. In 2008, there were about 110,000 new dialysis patients (United States Renal Data System 2010).<sup>2</sup>

In 2009, about 340,000 dialysis beneficiaries were covered by fee-for-service (FFS) Medicare. Compared with all Medicare beneficiaries, dialysis FFS beneficiaries are disproportionately younger and African American. About 38 percent of dialysis FFS beneficiaries are African American, three-quarters are less than 75 years old, and more than 45 percent are dually eligible for Medicare and Medicaid benefits. In recent years, the share of dialysis beneficiaries in Medicare Advantage (MA) plans has increased.<sup>3</sup> Between 2005 and 2008, enrollment in MA by ESRD beneficiaries doubled to about 40,000 beneficiaries.<sup>4</sup> Recent data from the Medicare Current Beneficiary Survey suggest that a small proportion (9 percent) of all FFS dialysis beneficiaries lack any supplemental insurance.

Data from CMS’s facility survey indicate that most dialysis patients (about 95 percent) are covered by Medicare. The share of dialysis patients not covered by Medicare between 2003 and 2008 (the most recent five-year period for which data are available) remained relatively steady, between 4 percent and 5 percent. Although most dialysis patients are Medicare covered, Medicare is the secondary payer for about one-quarter of new dialysis patients who are insured by an employer group health plan (EGHP) at the time they are diagnosed with ESRD. If an EGHP covers a beneficiary at the time of ESRD diagnosis, it is the primary payer for the first 33 months of care (as long as the individual maintains the EGHP coverage). EGHPs include health plans that beneficiaries were enrolled in through their own

**FIGURE  
6-1****Per capita spending for composite rate services and dialysis drugs, 2004–2009**

Note: FFS (fee-for-service), ESAs (erythropoiesis-stimulating agents). ESAs include erythropoietin and darbepoetin alfa.

Source: MedPAC analysis of claims submitted by dialysis facilities to CMS.

employment or through a spouse's or parent's employment before becoming eligible for Medicare due to ESRD.

Between 2006 and 2008, the rate of new cases of ESRD declined from 362 cases per million population to 351 per million, partly due to improvements in the care of diabetes, the leading underlying cause of ESRD (Burrows et al. 2010, United States Renal Data System 2010). By contrast, between 1995 and 2006, the rate of new ESRD cases increased each year. Data from the mid-1990s also suggest a trend toward starting ESRD patients on dialysis earlier in the course of chronic kidney disease across all age and racial groups (United States Renal Data System 2010). Researchers have questioned this early initiation of dialysis in patients with late-stage chronic kidney disease, concluding that it was not associated with an improvement in survival or in clinical outcomes (Cooper et al. 2010).<sup>5</sup>

Most dialysis beneficiaries receive care in freestanding dialysis facilities. Such facilities account for 90 percent of all facilities and treat about 92 percent of dialysis beneficiaries. The two largest dialysis organizations provide the major portion of Medicare-covered FFS

dialysis services: In 2009, they operated about 60 percent of all facilities and treated about two-thirds of all FFS dialysis beneficiaries.

Since 1983, Medicare pays dialysis facilities a predetermined payment for each dialysis treatment they furnish. Under the prospective payment—the composite rate—Medicare covers the cost of some (but not all) services associated with a single dialysis treatment, including nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs. In addition, Medicare pays separately for certain drugs and laboratory tests that have become a routine part of care since 1983. Since 2005, Medicare has paid providers an add-on payment to the composite rate. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created this add-on payment by shifting some of the payments previously associated with separately billable dialysis drugs to the composite rate (through the add-on payment) and mandated that these changes occur in a budget-neutral manner. Pursuant to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS will phase in a modernized prospective payment system (PPS) that broadens the dialysis payment bundle beginning in 2011 and implements a quality incentive program (QIP) in 2012.

In 2009, payment for composite rate services (including the add-on payment) averaged nearly \$160 per treatment, while payment for drugs used to treat conditions resulting from the loss of kidney function (referred to in this chapter as dialysis drugs) averaged about \$77 per treatment. The Commission's Payment Basics provides more information about Medicare's method for paying for outpatient dialysis services (available at [http://medpac.gov/documents/MedPAC\\_Payment\\_Basics\\_10\\_dialysis.pdf](http://medpac.gov/documents/MedPAC_Payment_Basics_10_dialysis.pdf)).

**Medicare spending on outpatient dialysis services**

In 2009, Medicare spending for dialysis services, including dialysis drugs, totaled about \$9.2 billion, an increase of 7 percent compared with 2008. These expenditures averaged about \$27,000 per beneficiary. Freestanding facilities accounted for 91 percent of the spending total (about \$8.3 billion in 2009). About 70 percent of all treatments furnished by freestanding facilities are reimbursed by FFS Medicare; other payers, including commercial payers, state Medicaid agencies, and the Department of Veterans Affairs, reimburse the remainder.

During the most recent five-year period for which expenditure data are available (2004–2009), per beneficiary payments (for composite rate services and dialysis drugs) to dialysis facilities grew by about 2 percent per year (Figure 6-1). During this period, per capita expenditures for composite rate services grew by 5 percent per year while expenditures for dialysis drugs fell by 3 percent per year. The decline in spending on dialysis drugs is partly due to MMA provisions that, beginning in 2005, increased Medicare’s payment rate for composite rate services but lowered the rate for dialysis drugs.<sup>6</sup> Since 2006, the agency pays 106 percent of the average sales price for dialysis drugs.

Despite the decrease in the payment rate, the total volume of dialysis drugs (holding price constant) increased between 2004 and 2007. Between 2007 and 2008, the volume of most dialysis drugs continued to increase with one notable exception. The volume of erythropoiesis-stimulating agents (ESAs) declined during this period. ESAs are drugs (erythropoietin and darbepoetin alfa) used to treat anemia, a common condition among dialysis patients, and account for about 70 percent of spending on dialysis drugs. The decline in ESA volume was linked to (1) changes in CMS’s payment policies for ESAs and (2) new clinical evidence about the appropriate use of ESAs. However, between 2008 and 2009, the total volume and per capita spending for dialysis drugs (including ESAs) increased.

### **A new dialysis prospective payment method began in 2011**

MIPPA modernized the payment method by including dialysis drugs for which providers previously received separate payments in the payment bundle beginning in 2011 and requiring that CMS implement a QIP beginning in 2012.

MIPPA’s provisions are consistent with the Commission’s long-standing recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could 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 formerly billed separately and by linking payment to quality. The new bundled rate is designed to create incentives for facilities to furnish services more efficiently by reducing incentives inherent in the former payment method to overutilize drugs.

CMS’s implementation of the MIPPA provisions makes three key changes to the outpatient dialysis payment method. Table 6-1 (p. 124) compares the new payment method provisions with the former payment method.

### **Broadening the payment bundle**

The first change to the payment method concerns definition of the payment bundle. Beginning in 2011, the dialysis payment bundle is expanded to include:

- composite rate services,
- Part B injectable dialysis drugs furnished by the facility and their oral equivalents paid for under Part D,
- 53 ESRD-related laboratory services,
- Part B separately billable equipment and supplies furnished by the facility,
- selected ESRD-related oral-only Part D drugs, and
- self-dialysis training services.

Until 2014, CMS will continue to pay for the oral-only ESRD-related drugs under Part D. This delay will enable the agency to complete an evaluation of the drugs’ pricing data and address operational concerns about including oral-only drugs in the broader payment bundle. In 2011, the bundled base rate is set at \$229.63. While the new PPS substantially broadens the payment bundle, facilities will continue to be paid for each dialysis treatment they furnish. MIPPA suggests that the Secretary can augment the payment bundle over time when new medical innovations, including drugs and devices, related to the treatment of ESRD become available. The law specifies that, in addition to composite rate services and dialysis drugs, the dialysis payment bundle includes other items and services that were not previously included in the composite rate bundle that are furnished for treatment of ESRD.

### **Increasing use of payment adjusters**

The new payment method increases the number of beneficiary-level and facility-level payment adjusters. MIPPA gave the Secretary the authority to adjust the payment rate by including factors that affect providers’ costs. The new PPS augments the current beneficiary-level adjusters used for adults—age and body mass—by including the presence of three acute and three chronic comorbidities and onset of dialysis for the first four months of dialysis treatment. For pediatric beneficiaries, the new PPS adjusts payment by age and dialysis method.



**TABLE  
6-1**

**New dialysis payment method broadens the payment bundle and includes more beneficiary-level adjustments, a low-volume adjustment, and payment for high-cost outliers**

<b>Payment method feature</b>	<b>Composite rate payment method: 1983–2010</b>	<b>New outpatient dialysis PPS: 2011 and beyond</b>
Payment bundle	Composite rate services, which include: nursing, dietary counseling and other clinical services, dialysis equipment and supplies, social services, and certain laboratory tests and drugs.	<ul style="list-style-type: none"> <li>• Composite rate services</li> <li>• Separately billable (Part B) injectable dialysis drugs and their oral equivalents</li> <li>• ESRD-related laboratory tests</li> <li>• Selected ESRD-related Part D drugs</li> </ul>
Unit of payment	Single dialysis treatment	Single dialysis treatment
Add-on payment to the composite rate	Yes	None
Self-dialysis training services adjustment	Yes	Yes
Beneficiary-level adjustments	<ul style="list-style-type: none"> <li>• For adults: age and body mass</li> <li>• For pediatric beneficiaries: none</li> </ul>	<ul style="list-style-type: none"> <li>• For adults: age, dialysis onset, body mass, 6 comorbidities</li> <li>• For pediatric beneficiaries: age and dialysis method</li> </ul>
Facility-level adjustments	<ul style="list-style-type: none"> <li>• Wage index</li> </ul>	<ul style="list-style-type: none"> <li>• Wage index</li> <li>• Low-volume adjustment</li> </ul>
Outlier policy	None	Applies to the portion of the broader payment bundle comprising the drugs and services that were formerly billed separately
Quality incentive program	None	Begins in 2012
Update	No statutory provision	Begins in 2012, set at ESRD market basket less productivity adjustment

Note: PPS (prospective payment system), ESRD (end-stage renal disease).

Source: MedPAC analysis of CMS 2010 final ESRD rule (Centers for Medicare & Medicaid Services 2010).

Two facility-level adjusters are included under the new payment method. The first one is new and targets low-volume facilities by including an 18.9 percent adjustment to the base payment rate to account for the higher costs that these facilities incur. A low-volume facility is defined as one that furnishes fewer than 4,000 treatments (including those for non-Medicare patients) in each of the three years before the payment year and that has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. Facilities under common ownership and within 25 road miles of each other are treated as if they were one unit when applying the low-volume adjustment; however, facilities certified for Medicare participation before January 1, 2011, are exempt from this provision.

CMS projections suggest that this adjustment should disproportionately increase the payments of rural facilities. Dialysis facilities in rural areas account for about 25 percent of all facilities while CMS projects that about 45 percent of low-volume facilities are located in rural areas (Centers for Medicare & Medicaid Services 2010).

The second facility-level adjuster—the wage index—was used under the former payment method. It uses the acute care hospital wage index to adjust payments to reflect local market prices for labor. Although MIPPA gave the Secretary the flexibility to implement a facility-level adjustment based on rural location, CMS is not implementing such an adjustment because the low-volume adjustment reduces the need to do so.



The new payment method will be phased in over four years; facilities were permitted to bypass the transition and opt into the new payment method if they notified CMS by November 1, 2010.

In 2011, CMS applies two budget-neutrality factors to ensure that total ESRD payments remain budget neutral, as specified by MIPPA. The first factor implements the statutory provision that total payments in 2011 must be equal to 98 percent of the estimated total payments for dialysis services that would have been made under the former payment method. The second factor is designed to ensure that overall program spending does not increase as a result of the provision that permits facilities to opt into the new payment method (and bypass the four-year transition period). This transitional budget-neutrality factor reduces all facilities' payments by 3.1 percent. To calculate the transition adjuster, CMS estimated that 43 percent of facilities would opt out of the transition period and choose to be paid under the new payment system.

### **Implementing a quality incentive program**

The ESRD QIP mandated in MIPPA begins in 2012. The ESRD QIP, Medicare's first payment incentive program, uses clinical performance outcomes that dialysis facilities submit on their claims. Under MIPPA, facilities that do not meet the performance standard will receive up to a 2 percent reduction in their payment rate. The three performance measures for 2012 are:

- **Anemia management:** Percentage of beneficiaries with an average hemoglobin concentration less than 10 grams/deciliter (g/dL). The Food and Drug Administration (FDA) recommends that patients treated with ESAs achieve a target hemoglobin value between 10 g/dL and 12 g/dL.
- **Anemia management:** Percentage of beneficiaries with an average hemoglobin rate greater than 12.0 g/dL. The labeling instructions for ESAs state that patients with chronic renal failure experience an increased risk for death and serious cardiovascular events when administered ESAs with a target hemoglobin value of greater than 13 g/dL.
- **Hemodialysis adequacy:** Percentage of beneficiaries with an average urea reduction ratio (URR) greater than 65 percent. Individuals with a URR value of less than 65 percent may not have sufficient wastes removed from their bloodstream during dialysis. A

larger percentage of patients with an average URR above 65 percent suggests better dialysis adequacy.

CMS has developed a methodology for calculating facility-level scores under the QIP. A facility's total performance score can range from 0 to 30 points, with each measure worth a maximum of 10 points.<sup>7</sup> To calculate each facility's score, CMS will weight the hemoglobin measure assessing the percentage of beneficiaries with an average hemoglobin less than 10 g/dL as 50 percent of the total score. The remaining 50 percent of the score will be divided equally between the two other measures. Under MIPPA, the performance standard with respect to 2012 payment is the lesser of (1) the facility-specific rate for each measure in 2007 or (2) the 2008 national performance rate of all facilities for each of these measures.

A sliding scale exists for payment reductions linked to QIP performance in 2012. Facilities need to achieve a minimum score of 26 points to avoid a payment reduction. The payment reduction for scores between 21 and 25 points is 0.5 percent; between 16 and 20 points, 1.0 percent; between 11 and 15 points, 1.5 percent; and between 0 and 10 points, the full 2.0 percent. CMS estimates that about one-quarter of all facilities will receive some payment reduction, with only 0.7 percent of all facilities receiving a 2 percent payment reduction in 2012 (Centers for Medicare & Medicaid Services 2011). Because reductions will be applied to facilities' monthly Medicare payments, beneficiaries' 20 percent coinsurance will reflect payment reductions that result from facilities' QIP performance scores.

### **Relationship between dialysis facilities and physicians who treat dialysis patients**

Because physicians can own facilities under the statute, physicians with financial or ownership interests share similar incentives with dialysis facilities to be efficient in furnishing services covered under the broader bundle. Disclosure of physician ownership of health care entities, as recommended by the Commission in 2009, will help CMS and other payers determine whether physician ownership might influence patient referrals, quality of care, volume, and overall spending (Medicare Payment Advisory Commission 2009).

Dialysis facilities depend on strong relationships with physicians, who typically are responsible for admitting patients to the facility and prescribing their treatments and drugs. Under the old and new payment methods,

relationships between the companies that own dialysis facilities and physicians must comply with the Anti-Kickback Statute, which prohibits the offer of payment or receipt of anything of value to induce the referral of patients for services paid for by federal health programs. Another statute, the Stark Law, restricts compensation relationships between physicians and entities that provide certain “designated health services.” Designated health services do not include composite rate services and most dialysis drugs. Thus, physicians are permitted to own facilities, participate in joint ventures, and have compensation relationships with dialysis facilities. In addition, many physicians who treat dialysis patients have medical director agreements with dialysis facilities. Medicare’s safety standards (conditions for coverage) require dialysis facilities to have a medical director.

Examples of financial relationships that one of the large dialysis chains reported in its public annual filing with the U.S. Securities and Exchange Commission include the following:

- The chain enters into compensation arrangements with physicians, including medical director agreements.
- Some of the chain’s facilities are leased from entities in which referring physicians hold interests.
- Some facilities sublease space to referring physicians.
- Some of the chain’s referring physicians own equity interests in companies that operate their dialysis facilities (DaVita Inc. 2010a).

Another company explains that it partners with physicians in developing and operating dialysis facilities. This regional chain has established a network of more than 40 independent dialysis centers that are individually controlled by one or more physician partners, yet they share resources and management expertise, including collective buying power (Innovative Dialysis Systems 2010).

### **Future topics**

As CMS phases in the new payment method, the Commission will continue its annual assessment of payment adequacy to providers of ESRD care. In particular, the Commission intends to focus on dialysis care in rural and other isolated areas, consumer information, the new quality incentives, payment adjusters, and payment updates.

### **Access to dialysis care in rural and other isolated areas**

We intend to monitor access to dialysis care in rural and other isolated areas. In this chapter, we examine several aspects of rural access, including the growth in dialysis stations and changes in the distances that beneficiaries travel to obtain dialysis care. In addition, the Patient Protection and Affordable Care Act of 2010 requires the Commission to evaluate Medicare payments to facilities in rural areas as well as access to and the quality of care in rural areas. The mandated report, which is due to the Congress on June 15, 2012, will include a discussion of access to dialysis care.

### **Information on the quality of dialysis care available to patients and the public**

The Commission has previously discussed the importance of monitoring the use of services and quality of care under the new PPS (Medicare Payment Advisory Commission 2003). CMS’s Dialysis Compare website provides facility-level information on dialysis adequacy, anemia management, and mortality. The agency could augment these data with other facility-level measures that it already collects (and provides to facilities) on other renal-related outcomes, such as septicemia and access-related infections, vascular access management, and rate of transplantation.<sup>8</sup> An independent nonprofit group recently made these data available on its website (ProPublica 2010). In addition to posting these renal-related outcomes, posting information on facilities’ compliance with Medicare’s health and safety standards, as CMS does for nursing homes, will help support beneficiaries’ decisions.

Although currently unavailable, information on patients’ satisfaction with their care is another measure that will help support beneficiaries’ decisions and may improve the patient-centeredness of their care. An ongoing mechanism for monitoring patient satisfaction can also serve as a way of surfacing patient concerns that complaint systems do not. The Commission and the Office of Inspector General recommended that CMS collect and analyze information on a regular basis on patients’ satisfaction with the quality of and access to care (Medicare Payment Advisory Commission 2000, Medicare Payment Advisory Commission 2003, Office of Inspector General 2000). Consumer testing of the Dialysis Facility Compare website indicated that consumers most frequently requested patient satisfaction information about the care given in dialysis facilities (Centers for Medicare & Medicaid Services 2008).

A Consumer Assessment of Healthcare Providers and Systems (CAHPS<sup>®</sup>) survey is available that captures data on in-center hemodialysis patients' perspectives on care provided by doctors, dialysis center staff, and the dialysis facility. CMS and the Agency for Healthcare Research and Quality jointly developed the CAHPS instrument during the past decade

Although patient satisfaction is among the measures that facilities must assess under Medicare's conditions for coverage, CMS does not require facilities to use the CAHPS instrument for their in-center hemodialysis patients (Centers for Medicare & Medicaid Services 2008).<sup>9</sup> CMS stated that voluntary use of the CAHPS instrument would increase as the renal community becomes more experienced in using the survey instrument.

**Quality incentive program** The Commission intends to monitor the effect of the ESRD QIP on dialysis facilities and beneficiaries and evaluate the need for including additional incentives to ensure quality improvement. In 2004, the Commission recommended that ESRD payment be linked to the quality of care furnished by providers and that such a program redistribute payments based on how providers perform but should not result in lower aggregate payments (Medicare Payment Advisory Commission 2004a). Under MIPPA, facilities that do not meet the performance standard will receive up to a 2 percent reduction in their payment rate. CMS estimates that totaling all the payment reductions for the one-quarter of all facilities expected to receive a reduction leads to a total payment reduction of approximately \$17.3 million in 2012, representing 0.2 percent of total ESRD payments (Centers for Medicare & Medicaid Services 2011).

The Commission remains concerned that the QIP does not hold facilities accountable for the quality of care furnished to all their patients (Medicare Payment Advisory Commission 2010a). For example, it does not measure anemia management for patients who do not receive ESAs, nor does it measure dialysis adequacy for home dialysis patients or hemodialysis patients who receive more than three treatments per week, and it excludes pediatric patients (under 18 years of age). Furthermore, the QIP may not sufficiently value the dialysis adequacy measure. Patients who receive insufficient dialysis are at greater risk of mortality and other serious events than patients whose treatment meets adequacy guidelines. Although the proportion of patients who currently receive adequate dialysis is high and has increased over time, there

is a greater incentive under a PPS to undertreat patients than to overtreat them

Finally, the Commission believes that the measures used in the ESRD QIP initiatives should evolve (Medicare Payment Advisory Commission 2005). In the future, CMS should consider linking payment to measures associated with improved patient outcomes, such as lower rates of renal-related hospitalizations and emergency room visits (Medicare Payment Advisory Commission 2010a). As we noted previously, to link some potential measures to ESRD payment, such as use of home dialysis and arteriovenous fistulas, the recommended type of vascular management for hemodialysis patients, it would be necessary to identify those patients who are not appropriate candidates because of the presence of certain clinical morbidities (for both measures) and social circumstances and personal preferences (for home dialysis) (Medicare Payment Advisory Commission 2007). Thus, calculation of the QIP measure might need to account for such patients.

**Transitional budget-neutrality adjustment** A greater number of facilities may have elected to opt out of the transition to the new payment method than CMS anticipated. According to an association of renal-related stakeholders, about 90 percent of facilities have decided to be paid under the new payment method. As a result, the 3.1 percent budget-neutrality adjustment may be set too high. As of this writing, CMS has not announced the number of facilities that have opted into the new payment method.

**Low-volume payment adjustment** The Commission intends to monitor the impact of the low-volume payment adjustment, including which facilities are benefiting from it. For qualifying existing facilities, the payment adjustment is applied without regard to the distance to the next closest facility. Thus, this payment adjustment can be applied to two or more small facilities (that were in existence and certified for Medicare participation before January 1, 2011) located within close proximity—even side by side—to one another.

**Updating the new PPS payment rate** The Secretary is required to update the payment rate for the broader bundle to reflect changes over time in the prices of goods and services used to provide ESRD care. For several items in the market basket, including dialysis drugs, electricity, natural gas, laboratories, and supplies, CMS is using the producer price index (PPI), a family of indexes that

**TABLE  
6-2**

**The total number of dialysis facilities is growing; for-profit and freestanding dialysis providers are a larger share over time**

	2010	Average annual percent change	
		2005-2010	2009-2010
Total number of dialysis facilities	5,413	3.6%	3.9%
Total number of hemodialysis stations	95,489	3.9	4.4
Urban hemodialysis stations	76,316	3.8	4.5
Rural hemodialysis stations	19,173	4.3	4.2
Mean number of hemodialysis stations per facility	17.6	0.3	0.5

	Percent of facilities	Percent of Medicare dialysis treatments	Average annual percent change in the number of facilities	
Nonchain	20%	15%	-0.3%	0.8%
Affiliated with any chain	80	85	4.7	4.7
Affiliated with one of the two large dialysis organizations	61	65	3.8	5.5
Rural	24	19	3.2	2.9
Urban	76	81	3.7	4.2
Freestanding	90	90	4.5	4.8
Hospital based	10	10	-2.5	0.0
For profit	82	87	4.6	5.2
Nonprofit	18	13	-0.6	-1.7

Note: Percent of Medicare dialysis treatments uses data derived from claims submitted by dialysis facilities for 2009 (the most recent year available). Nonprofit includes those designated as either nonprofit or government.

Source: Compiled by MedPAC from the 2005, 2009, and 2010 Dialysis Facility Compare database from CMS and 2009 claims submitted by dialysis facilities.

measures the average change over time in selling prices received by domestic producers of goods and services.

The Office of Inspector General contended that the “PPI—commodities pharmaceuticals for human use, prescription” will not accurately capture price changes incurred by dialysis facilities for providing injectable dialysis drugs previously paid for under the average sales price methodology or for oral drugs previously paid for under Part D (Office of Inspector General 2010). CMS disagreed, stating that PPIs are the preferable price proxies for goods and services that facilities purchase as inputs in producing dialysis services, since these facilities generally make purchases in the wholesale market. CMS argued that future growth in dialysis drug prices will more closely reflect market-based price drivers, such as those measured by the PPI. Dialysis drugs represent one-quarter of the market basket. Thus, how these prices are updated will

affect the accuracy of dialysis payments. In next year’s assessment of payment adequacy, the Commission will assess the growth of the PPI for pharmaceuticals versus other proxies measuring the growth in drug prices, such as changes in average sales price.

**Providers of outpatient dialysis services**

During the past five years, an increasing proportion of dialysis facilities are freestanding, owned by publicly traded companies, operated by a chain (i.e., multifacility enterprises), and for profit (Table 6-2). By chain, we mean facilities operated under common ownership; CMS’s Dialysis Facility Compare database indicates “whether or not the facility is owned or managed by a chain organization.” Recently, the dialysis sector has evolved into an oligopoly, in which a small number of firms supply the major portion of an industry’s output. In 2005 and 2006, the four largest dialysis organizations



merged into two for-profit organizations. Together the two largest dialysis organizations (Fresenius Medical Care North America and DaVita) account for 60 percent of all facilities and for nearly 70 percent of freestanding facilities. However, industry consolidation continues:

- In November 2010, two dialysis companies, Renal Advantage and Liberty Dialysis, agreed to combine to form the third largest provider of dialysis services, caring for more than 19,000 patients in 260 facilities in 32 states.
- In June 2010, U.S. Renal Care Inc. acquired Dialysis Corporation of America. As a result of this consolidation, U.S. Renal Care Inc. will care for 5,500 patients in 84 facilities in 9 states.

The recent trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that there are efficiencies and economies of scale in providing dialysis care.

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## **Are Medicare payments adequate in 2011?**

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To address whether payments for the current year (2011) are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the coming year (2012), we examine several indicators of payment adequacy. Specifically, we assess beneficiaries' access to care by examining the capacity and supply of dialysis providers and changes over time in the volume of services provided, quality of care, providers' access to capital, and the relationship between Medicare's payments and providers' costs. Most of our payment adequacy indicators for dialysis services are positive: Provider capacity is sufficient, volume growth has kept pace with beneficiary growth, some quality improvements have occurred, and provider access to capital is sufficient. The Medicare margin for composite rate services and dialysis drugs was 3.1 percent in 2009, and we project it will be 1.3 percent in 2011.

### **Beneficiaries' access to care: Indicators continue to be generally favorable**

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand, changes in patients' ability to obtain different types of dialysis, and

changes in the volume of services—shows that beneficiary access to care remains favorable. Although African Americans and beneficiaries dually eligible for Medicare and Medicaid were overrepresented in facilities that closed in 2009, overall, facility closures affected less than 1 percent of these beneficiaries.

### **Providers' capacity has kept pace with beneficiary demand**

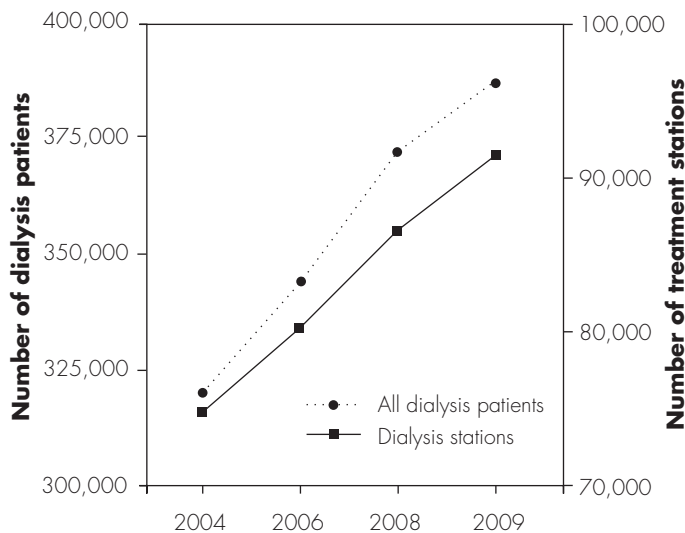
Since 2005, freestanding facilities have increased by more than 4 percent annually and currently account for 90 percent of all facilities (Table 6-2). During this period, for-profit facilities have increased at 4.6 percent per year and account for 82 percent of all facilities. The number of hospital-based facilities decreased from 644 to 566 during this time. Most freestanding facilities (91 percent) are for profit; by contrast, most hospital-based facilities (96 percent) are nonprofit (data not shown). Most freestanding dialysis facilities (87 percent) are affiliated with a chain, whereas most hospital-based facilities (80 percent) are not (data not shown). In terms of size, as measured by the number of dialysis treatment stations, freestanding facilities are, on average, larger than hospital-based facilities (data not shown). In 2010, freestanding facilities had 18 dialysis stations, on average, while hospital-based facilities averaged 14 stations.

About one-quarter of dialysis facilities and stations are located in rural areas, while more than one-fifth of FFS dialysis beneficiaries reside in rural areas. Recent trends suggest that the gap in the annual growth rate between urban and rural facilities appears to be widening. During the past five years, the number of urban facilities increased by 3.7 percent per year, compared with 3.2 percent annual growth for rural facilities. Growth was even faster between 2009 and 2010, as the number of urban facilities increased by 4.2 percent per year, compared with 2.9 percent annual growth for rural facilities. In contrast, in these last two years, the number of hemodialysis stations grew at similar rates in rural and urban areas, after slightly faster annual growth between 2005 and 2010 in rural areas compared with urban areas (4.3 percent per year vs. 3.8 percent per year) (Table 6-2).

Growth in the number of dialysis stations and dialysis beneficiaries suggests that provider capacity has kept up with demand for care during the past decade. In the most recent five-year period for which data are available—between 2004 and 2009—the number of all dialysis patients (those in FFS Medicare, in MA, and not eligible

**FIGURE 6-2**

**Growth in the number of dialysis stations has kept pace with growth in the number of all dialysis patients**



Note: All patients include those individuals covered by Medicare under the fee-for-service and Medicare Advantage programs and individuals not covered by Medicare.

Source: Compiled by MedPAC from CMS's Dialysis Compare file, United States Renal Data System 2010, and data from Renal Network 13.

for Medicare) and dialysis treatment stations increased by 4 percent per year (Figure 6-2). During this period, annual growth in the number of treatment stations was faster than the 2 percent annual growth in the number of FFS dialysis beneficiaries.

**Access to different dialysis options has changed little over time**

Access to types of dialysis shows little change over time according to data from CMS. Between 1998 and 2010, at least 96 percent of facilities offered in-center hemodialysis and 46 percent offered some type of peritoneal dialysis—continuous cycle peritoneal dialysis or continuous ambulatory peritoneal dialysis. Between 2003 and 2010, the proportion of facilities offering home hemodialysis increased from 12 percent to 22 percent. In addition, industry data suggest that dialysis facilities are beginning to offer in-center nocturnal hemodialysis. For example, DaVita operated more than 115 nocturnal facilities in 2010 (representing about 8 percent of all its facilities) (DaVita Inc. 2010b).

Most patients receive dialysis in outpatient facilities. In 2008 (the most recent year for which data are available), 92 percent of dialysis patients received hemodialysis in a facility, while 7 percent received peritoneal dialysis (at home), and 1 percent received home hemodialysis (United States Renal Data System 2010). Between 1998 and 2008, the number of patients receiving hemodialysis in a facility increased by 5 percent per year, while the number of patients treated at home grew by less than 1 percent per year.

Fewer patients overall dialyzed at home in 2008 than in the mid-1990s. Factors contributing to this trend include patients' lack of knowledge about home-based dialysis and some physicians' lack of familiarity with home modalities, which may make them less likely to discuss this option with their patients. Medicare's payment method is also a factor in the decline in home-based methods. The profitability of separately billable dialysis drugs may have provided an incentive to focus on in-center programs rather than on home-based ones. On average, peritoneal dialysis patients use fewer dialysis drugs than in-center hemodialysis patients. Home dialysis offers several advantages related to quality of life and satisfaction. Compared with in-center hemodialysis, home dialysis is more convenient for patients because they do not have to travel and can dialyze on their own schedule. The new payment method could result in increased use of home methods. Providers' costs to furnish the most common home-based method—peritoneal dialysis—are less than for in-center hemodialysis. In addition, in 2010, Medicare began to pay for educating pre-ESRD beneficiaries about kidney disease. Early intervention, which includes educating patients about their treatment options and better management of chronic kidney disease patients (before they require dialysis), may reduce the substantial morbidity, mortality, and costs associated with ESRD (see text box).

During the past few years, the use of more frequent hemodialysis (furnished at home or in a center five to seven times per week compared with the typical three times a week regimen) has modestly increased. Interest in more frequent hemodialysis regimens has grown during the past decade because of studies showing improved outcomes and quality of life. According to CMS's facility survey, between 2004 and 2008, the number of patients receiving hemodialysis more than five times per week more than tripled to about 2,200 patients. Results of a study partly funded by the National Institutes of

## Earlier intervention and better management of chronic kidney disease before starting dialysis improves patients' outcomes

**B**etter management of chronic kidney disease before developing end-stage renal disease (ESRD) and the need for either dialysis or a kidney transplant is an important determinant of ESRD patients' outcomes. Researchers have shown that early referral to a multidisciplinary renal team before starting dialysis is associated with:

- increased provision of medical interventions, including angiotensin-converting enzyme inhibitors and blood sugar control, that delay disease progression;
- better management of renal-related complications, including malnutrition and osteodystrophy;
- decreased mortality risk in the first four months after starting dialysis (Bradbury et al. 2007);
- increased likelihood of being registered on the kidney transplant list and receiving a transplant (Winkelmayer et al. 2007); and
- improved preparation for renal replacement therapy, including educating patients about the different dialysis treatment options and having the recommended type of vascular access—an arteriovenous fistula.

A Commission analysis also showed that earlier referral of patients with chronic kidney disease to a nephrologist may reduce some of the morbidity associated with ESRD (Medicare Payment Advisory Commission 2004b). However, a substantial share of patients do not see a renal specialist until they are close to needing dialysis. For example, Kinchen and colleagues reported that 30 percent of patients were first seen by a nephrologist less than 4 months before initiation of dialysis (Kinchen et al. 2002).

Medicare has little effect on the pre-ESRD care furnished to individuals who are not already entitled to benefits. The lack of Medicare coverage primarily affects individuals under age 65, who are generally not eligible for Medicare benefits until the fourth month after starting dialysis (with the exception of individuals who undergo transplantation or who participate in a self-dialysis training program or already qualify for Medicare due to disability). Thus, it is not surprising that the uninsured (compared with the insured) were less likely to have seen renal specialists in the year before they initiated dialysis (Kinchen et al. 2002). In addition, race and a greater severity of comorbid disease were related to access to pre-ESRD care. African Americans (compared with whites) and individuals with greater severity of comorbid disease (compared with individuals with no or mild comorbid disease) were less likely to have seen renal specialists before they initiated dialysis (Kinchen et al. 2002). ■

Health showed that patients who received more frequent hemodialysis (six times per week compared with the conventional three times per week) had improvements in heart health and blood pressure as well as in overall health (National Institutes of Health 2010). The more frequent treatments also helped avoid excessive phosphate levels in the blood, which is often a problem for patients on dialysis. The only downside was that access to blood vessels needed to be adjusted about twice as often in patients who received more treatments. With the publication of these clinical trial results, the Commission will explore policy options for covering and paying for more frequent hemodialysis.

### **Types of facilities that closed and their effect on beneficiaries' access to care**

Each year, we look at the types of facilities that close and assess whether specific groups of beneficiaries are disproportionately affected. Specifically, we compare the characteristics of dialysis beneficiaries treated by facilities that were open in 2008 and 2009, that newly opened in 2009, and that closed in 2009.

Compared with facilities that remained open, facilities that closed in 2009 (about 60 units) were more likely to be hospital based and nonprofit, which is consistent with long-term trends in supply (as shown in Table 6-2, p. 128). The finding that facilities that opened in 2009



(about 270 units) were more likely to be freestanding and for profit is also consistent with the long-term trends in supply. Facilities that closed had less capacity than those that remained open (averaging 13 hemodialysis stations compared with 18 hemodialysis stations). Facility closures in rural areas did not appear to limit providers' capacity. Between 2008 and 2009, the number of hemodialysis stations in rural areas increased by about 4 percent, from about 18,400 stations to 19,200 stations.

Facility closures in 2009 did not appear to adversely affect elderly beneficiaries (75 years or older). Facilities that closed and those that remained in business had a similar share (24 percent to 25 percent) of elderly beneficiaries. Disease severity, as measured by the Charlson index, did not differ between facilities that closed and ones that remained in business.<sup>10</sup> However, facility closures in 2009 disproportionately affected African American beneficiaries and beneficiaries dually eligible for Medicare and Medicaid. Facilities that closed, compared with those that remained in business, treated greater proportions of African Americans (46 percent compared with 38 percent) and dual eligibles (51 percent compared with 48 percent). However, less than 1 percent of African American and dual-eligible beneficiaries were affected by closures. In addition, as we show in the next section, the travel distance for all African Americans and dual-eligible beneficiaries remained relatively constant between 2004 and 2008.

Elderly, African American, and dual-eligible beneficiaries continued to obtain care from the two large dialysis chains that serve the majority of FFS beneficiaries. In both 2008 and 2009, 23 percent of beneficiaries served by these chains were elderly, 40 percent were African American, and 47 percent were dual eligibles.

### **Travel distances for new FFS dialysis beneficiaries**

Another way to assess whether facility closures and consolidations affect beneficiaries' access to care is to look at changes in the distance new FFS dialysis beneficiaries travel to seek care.<sup>11</sup> Longer travel time to the dialysis unit, which creates a substantial burden for many patients, has been linked to decreased patients' adherence to the dialysis prescription and increasing mortality (Moist et al. 2008).

We calculated driving miles for new FFS dialysis beneficiaries in 2004, 2006, and 2008 using claims submitted by facilities to CMS, CMS's Renal Management Information System file, and Dialysis Compare. As shown

in Table 6-3, during this four-year period, median driving miles did not substantially change. Median driving distance was about 6 miles for all new FFS dialysis beneficiaries. For the three years examined, driving distances remained constant for beneficiaries in the 25th percentile of driving distances (3 miles) and for beneficiaries in the 75th percentile (13 miles). Older beneficiaries and African Americans traveled fewer median miles than younger beneficiaries and whites. As expected, beneficiaries residing in rural areas drove longer distances than beneficiaries residing in urban areas. Similar to the finding for all beneficiaries, the variability in travel distances, as measured by the 25th and 75th percentiles of driving distances, remained constant across the different beneficiary groups. Specifically, in all three years, driving distances ranged from 3 miles to 10 miles for African American beneficiaries, from 3 miles to 12 miles for elderly beneficiaries, and from 3 miles to 22 miles for rural beneficiaries.

### **Volume of services: Use of ESAs increased between 2008 and 2009**

To assess changes in the volume of dialysis services, we examined trends in the number of dialysis treatments furnished to beneficiaries and in the use of drugs administered during dialysis. For this analysis, we focused on the volume of services furnished by freestanding facilities, as they treat most dialysis beneficiaries.

Between 2008 and 2009, dialysis treatments furnished to FFS beneficiaries grew at an average annual rate that kept pace with the growth in the number of FFS dialysis beneficiaries. During this period, the number of dialysis treatments furnished by freestanding facilities grew by 4 percent per year, while the number of FFS dialysis beneficiaries grew by 4 percent per year.

To assess changes in erythropoietin volume (the ESA that accounts for more than 90 percent of ESA spending and about 70 percent of total drug spending), we held the drug payment rate constant and looked at the dollar change in the total volume of the products. In the most recent period for which data are available (2008–2009), the aggregate volume of erythropoietin increased by 6 percent. On a per capita basis, units per treatment of erythropoietin increased by 2 percent. This increase in the aggregate and per capita use of erythropoietin is in contrast to the slowdown in the use of this drug class between 2006 and 2008.<sup>12</sup>

A key question about higher ESA volume in 2009 is whether this trend is associated with improving beneficiaries' outcomes, including survival and use of

**TABLE  
6-3**

**Median driving miles did not change for new fee-for-service dialysis beneficiaries between 2004 and 2008**

	Median driving miles		
	2004	2006	2008
All			
Median	6.1 miles	6.1 miles	6.0 miles
(25th percentile–75th percentile)	(2.9–13.2)	(3.0–13.3)	(2.9–12.8)
Male	6.2	6.3	6.1
Female	5.9	6.0	5.9
Less than 45 years	7.1	6.3	6.5
45 to 64 years	6.1	6.2	5.8
65 to 74 years	6.3	6.3	6.3
75 years or older	5.6	5.9	5.8
White	6.9	7.0	6.8
African American	4.9	4.9	4.9
Other race	5.3	5.7	5.6
Dually eligible for Medicare and Medicaid	5.8	5.7	5.6
Resided in rural area	11.0	10.8	10.4
Resided in urban area	5.6	5.6	5.5

Source: MedPAC analysis of 2004, 2006, and 2008 claims data submitted by dialysis facilities and CMS's Renal Management Information System file.

inpatient hospital and emergency department services. Evidence in the peer-reviewed literature reports increased risk of cardiovascular morbidity and mortality among patients with chronic kidney disease (including predialysis patients and dialysis patients) who are prescribed higher doses of ESAs that target higher hematocrit/hemoglobin levels (Besarab et al. 1998, Pfeffer et al. 2009, Singh et al. 2006). Recently published studies support these findings. A new study reported that dialysis facilities that used larger (versus smaller) doses of ESAs in patients with hematocrit levels of 33 percent or higher had statistically elevated mortality risks (Brookhart et al. 2010). FDA officials called for randomized trials to assess the optimal hemoglobin target, dosing algorithm, and monitoring approach for patients with anemia from chronic kidney disease (Unger et al. 2010). In June 2010, CMS opened a national coverage analysis evaluating ESA use for treatment of anemia in adults with chronic kidney disease, including patients on dialysis and patients not on dialysis.

Volume for other dialysis drugs has also increased. Between 2008 and 2009, the aggregate volume of non-ESA drugs (holding price constant) increased by 6 percent.

**Quality of care: Some measures show progress, others need improvement**

The Commission assesses quality of care furnished to dialysis patients using a variety of measures (clinical performance measures and beneficiaries' outcomes) and from different perspectives (trends for all patients and by type of facility).

To assess how facilities meet Medicare's clinical performance measures, we use data from the Elab Project, in which nearly all dialysis facilities provide ESRD networks with patient-level laboratory data on clinical indicators, such as dialysis adequacy and anemia status for all the facility's patients treated. We use data from CMS's quality project, Fistula First, to monitor changes in the types of vascular access used by hemodialysis patients.

To assess trends in hospitalization, mortality, and renal transplantation overall for all patients and by facility type, we use data derived from claims by the U.S. Renal Data System.

The conclusions of this year's assessment of changes in dialysis quality are consistent with those in last year's report. Dialysis adequacy remains high and improvements have been made in the proportion of all patients meeting the anemia status recommendations developed by FDA and using the type of vascular access recommended by renal clinicians. Between 2003 and 2008, mortality, while high, trended downward and hospitalization rates remained about the same. Rates of kidney transplantation increased for Asians and Native Americans, remained about the same for African Americans, and decreased for whites. Some provider types achieved statistically significantly lower rates of standardized hospitalization and mortality rates than others.

### **Trends in clinical indicators of dialysis quality**

Data show that the quality of some aspects of dialysis care has remained high. Between 2003 and 2009, the proportion of dialysis patients receiving adequate dialysis (a measure of the effectiveness of the dialysis treatment in removing waste products from the body) remained high (Table 6-4). According to this measure, from 93 percent to 95 percent of hemodialysis patients and 88 percent to 90 percent of peritoneal dialysis patients during this period received adequate dialysis.

Also during this period, increasing proportions of dialysis patients had their anemia under control (i.e., with a mean hemoglobin between 10 g/dL and 12 g/dL). Nearly all dialysis patients have anemia because diseased kidneys often do not produce sufficient amounts of a hormone that stimulates red blood cell production, leading to the development of anemia. Providers furnish ESAs and intravenous iron to treat anemia.

In the 2003 to 2009 period, use of the recommended type of vascular access—arteriovenous (AV) fistula—also improved. Hemodialysis patients require vascular access—the site on the patient's body where blood is removed and returned during dialysis. The three basic types of vascular access are AV fistulas, AV grafts, and catheters.<sup>13</sup> For most patients, the AV fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow, lasts a long time, and has a lower complication rate than other types of access (National

Institute of Diabetes and Digestive and Kidney Diseases 2008). As shown in Table 6-4, the rate of sepsis is lowest for patients with an AV fistula, followed by those with an AV graft, and a catheter. Compared with AV graft patients, AV fistula patients undergo fewer declotting procedures, a minimally invasive procedure performed to improve blood flow in fistulas and grafts placed in the blood vessels of dialysis patients. CMS is leading a national quality initiative—Fistula First—with a goal of having fistulas placed in at least half of new hemodialysis patients and having a minimum of 66 percent of patients who continue dialysis using a fistula.

The level of albumin in the blood has been used by CMS and the ESRD networks as a marker of nutritional status for patients. Inflammation and infection can affect albumin levels. Importantly, researchers have found a strong inverse correlation between albumin levels and mortality. There has been little change in the percent of patients with a mean albumin level that equals or exceeds the recommendation of the National Kidney Foundation.

Clinical indicators related to the management of bone and mineral disorders, a frequent comorbidity of kidney failure, suggest some improvement between 2003 and 2007. About 46 percent of hemodialysis and peritoneal dialysis patients achieved the recommended range for phosphorous and calcium levels. Since 2007, the percentage of dialysis patients achieving the recommended range for these two measures has remained constant.

### **Trends in outcomes for dialysis patients**

In general, trends in outcomes—including mortality, access to kidney transplantation, and hospitalization—suggest that improvements in dialysis quality are still needed.

In the 2003–2008 period, overall adjusted mortality rates decreased but remained high among dialysis patients. By race, dialysis patients included in the “other” category (which includes Asian Americans and Native Americans) had the lowest adjusted mortality rate; this finding is a function of the lower mortality rate among Asian Americans. In contrast to the pattern seen in the general population, adjusted mortality was lower among African American dialysis patients than among whites (16.6 vs. 20.1 per 100 patient years, respectively, in 2008) (United States Renal Data System 2010). The presence of cardiovascular disease, which is the leading cause of death in dialysis patients, may explain some of the association of race with mortality in dialysis patients. Researchers have

**TABLE  
6-4****Dialysis clinical indicators and outcomes continue to improve for some measures**

<b>Outcome measure</b>	<b>2003</b>	<b>2005</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
Percent of in-center hemodialysis patients					
Receiving adequate dialysis	94%	93%	94%	95%	95%
Anemia measures					
Mean hemoglobin 10–12 g/dL	48	44	49	57	62
Mean hemoglobin ≥ 13 g/dL*	15	17	14	9	7
Mean hemoglobin < 10 g/dL*	6	5	6	6	6
Dialyzed with an AV fistula	33	39	47	50	53
Nutritional status	37	33	34	35	35
Phosphorous and calcium management	39	42	46	45	46
Percent of peritoneal dialysis patients					
Receiving adequate dialysis	N/A	90%	89%	88%	89%
Anemia measures					
Mean hemoglobin 10–12 g/dL	45%	44	48	52	57
Mean hemoglobin ≥ 13 g/dL*	21	22	18	14	12
Mean hemoglobin < 10 g/dL*	7	7	7	9	10
Nutritional status	21	20	20	19	18
Phosphorous and calcium management	40	44	46	45	47
	<b>2003</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>
Vascular access complications rate per hemodialysis patient year					
Catheter					
Sepsis events*	2.9	2.2	1.6	2.3	N/A
AV graft					
Declotting procedures*	0.4	0.4	0.4	0.5	N/A
Sepsis events*	0.7	0.8	0.7	0.6	N/A
AV fistula					
Declotting procedures*	0.1	0.1	0.1	0.1	N/A
Sepsis events*	0.5	0.4	0.4	0.5	N/A
Percent of prevalent dialysis patients wait-listed for a kidney					
All	15.2%	15.9%	16.3%	16.8%	17.0%
White	14.2	14.8	15.2	15.7	15.9
African American	15.5	16.3	16.7	17.3	17.5
Native American	14.0	14.2	14.5	15.0	15.5
Asian American	24.4	25.2	25.2	25.6	25.6
Renal transplant rate per 100 dialysis patient years					
All	4.8	4.8	4.8	4.4	4.2
White	5.9	5.7	5.6	5.1	4.8
African American	3.1	3.2	3.2	3.0	2.9
Native American	3.3	3.4	4.6	4.4	4.3
Asian American	5.3	5.5	6.6	7.5	7.2
One-year survival for new dialysis patients					
All	78.1%	78.9%	79.6%	79.9%	N/A
White	77.0	77.7	78.4	78.6	N/A
African American	79.3	80.3	80.9	81.5	N/A
Other	84.2	85.0	85.3	86.4	N/A
Annual mortality rate per 100 dialysis patient years					
All*	21.4	20.5	20.1	19.3	18.6
White*	23.2	22.2	21.7	20.8	20.1
African American*	19.2	18.7	18.1	17.3	16.6
Other*	16.4	15.4	14.9	14.2	13.7
Inpatient admission rate per dialysis patient					
All*	2.0	2.0	2.0	1.9	1.9
White*	2.0	2.0	2.0	1.9	1.9
African American*	2.0	2.0	2.0	2.0	1.9
Native American*	2.0	1.9	1.8	1.8	1.7
Asian American*	1.4	1.5	1.4	1.4	1.4

Note: g/dL (grams/deciliter), N/A (not available), AV (arteriovenous). Other includes Asian Americans and Native Americans. Data on dialysis adequacy, use of fistulas, and anemia management represent percent of patients meeting CMS's clinical performance measures. United States Renal Data System adjusts data by age, gender, race, and primary diagnosis of end-stage renal disease.  
\* Lower values indicate higher quality.

Source: Compiled by MedPAC from the Elab Project Report, Fistula First, and the United States Renal Data System (Fistula First 2011, Renal Network 11 2011, United States Renal Data System 2010).

## Trends in kidney transplantation

**K**idney transplantation is a life-saving medical procedure for which the demand far exceeds the transplantable organ supply. Transplantation improves clinical outcomes compared with dialysis. When no living kidney donor is available, end-stage renal disease (ESRD) patients must rely on the limited supply of cadaveric donor organs. Although the principle of equity is emphasized in the distribution of this limited resource, several studies have documented that kidney transplantation rates differ by patients' demographic and socioeconomic characteristics.

For example, access to kidney transplantation and organ donation rates vary by race. Data from the United States Renal Data System show that in 2008:

- White ESRD patients accounted for 61 percent of ESRD patients and received 65 percent of transplants.
- African Americans accounted for 32 percent of ESRD patients and received 24 percent of transplants.
- Asian Americans and Native Americans together accounted for 6 percent of ESRD patients and received 10 percent of transplants.

However, in the recent five-year period between 2003 and 2008, transplantation rates changed somewhat across racial groups. Transplantation rates increased for

Asian Americans and Native Americans (Table 6-4). During this period, the rates for African Americans declined slightly from 3.1 to 2.9 transplants per 100 dialysis patients, while the rates for whites declined even more, from 5.9 to 4.8 per 100 dialysis patients.

The factors affecting access to kidney transplantation are complex. Unequal transplantation rates result in part from differences in the clinical appropriateness of patients as candidates for transplantation. Some patients are not able to receive a transplant because of the presence of medical contraindications—such as a recent history of substance abuse, the presence of cancer, a serious infection (including from dental disease), and significant cardiovascular disease.

Lower rates of renal transplantation, particularly among minority patients, also partly reflect the immunologic (including blood type and antibodies in the blood) matching process of donors to recipients. Reducing the number of biological mismatches improves the outcomes of kidney transplantation; as a result, the matching process gives priority to candidates who have fewer mismatches. Researchers have reported that because of racial and ethnic differences in the frequency of alleles (any one of two or more genes) at a given site on a chromosome, whites are more likely than people in other racial and ethnic groups to find a good match in the cadaver kidney pool (Roberts et al. 2004). This difference, coupled with the matching process, increases the transplantation rate among white

*(continued next page)*

reported that, compared with African American dialysis patients, white dialysis patients are at increased risk of developing atherosclerotic cardiovascular disease (even after adjusting for traditional cardiovascular and dialysis-related risk factors) and that this increased risk may contribute to the higher risk of mortality in whites than in African Americans (Parekh et al. 2005).

We looked at several measures that examine access to kidney transplantation, because it is widely believed that kidney transplantation is the best treatment option for ESRD patients. Transplantation reduces mortality and improves patients' quality of life (Eggers 1988, Kasiske

et al. 2000, Laupacis et al. 1996, Ojo et al. 1994). The proportion of dialysis patients accepted on the kidney transplant waiting list showed little change over time (Table 6-4, p. 135).

We also examined rates of kidney transplantation in the 2003–2008 period. In 2008, the United States Renal Data System (USRDS) reported that 17,413 individuals underwent transplantation, which represents about 22 percent of the 77,684 patients wait-listed for a kidney in that year. Between 2003 and 2006, rates of kidney transplantation remained relatively steady (Table 6-4, p. 135) (United States Renal Data System 2010). However,



## Trends in kidney transplantation (cont.)

candidates and reduces access for candidates with less common blood types and antibodies in the blood, including those who are members of minority groups (Roberts et al. 2004).

Differences in access may also stem from differences in transplants from live donors. In 2008, transplants from live donors accounted for about 34 percent of procedures, while kidney transplants from deceased donors accounted for 65 percent of procedures (United States Renal Data System 2010). By race, whites accounted for 74 percent of live donor procedures, compared with 14 percent for African Americans and 11 percent for Asian Americans and Native Americans. Researchers have noted that there are fewer living donors among African Americans, increasing their dependence on cadaver organs (Young and Gaston 2000). According to the Health Resources and Services Administration, because certain blood types are more common in ethnic minority populations, increasing the number of minority live donors can increase the frequency of transplants in minority populations (Health Resources and Services Administration 2010).

Differences in kidney transplantation rates may also reflect patient and provider factors. Possible patient-level factors include lack of knowledge about transplantation, concerns about surgery and adverse effects of medication, and mistrust of the medical system. Provider-level factors that may affect access to kidney transplantation include clinicians' subconscious bias and transplant center characteristics.

However, in analyses controlling for some of these demographic and clinical characteristics, differences in access to kidney transplantation persisted. Researchers have examined the sequential steps that lead to transplantation (a patient's medical suitability and possible interest in a transplant, definite interest in a transplant, completion of the pretransplant workup, and moving up the waiting list to eventual transplantation) and have found that access to cadaveric kidney transplantation is significantly related to patients' race, sex, and income. For example, compared with whites, men, and higher income patients, African Americans, women, and lower income patients were less likely to complete the pretransplant workup (Alexander and Sehgal 1998). After referral to a transplant center, the three factors that medical professionals evaluate to determine a good candidate are the individual's physical and mental health and whether the individual's insurance pays for the medicines needed after transplantation (American Society of Transplantation 2006, National Institute of Diabetes and Digestive and Kidney Diseases 2008).

To increase the number of transplants overall, there is now an expanded donor waiting list in addition to the standard donor waiting list. A kidney from the expanded donor list is from an older donor or an individual who has less-than-normal kidney function. To increase transplants among minority populations, some researchers have advocated eliminating the priority given to one type of immunologic matching (Roberts et al. 2004). ■

between 2006 and 2008, the rate of kidney transplantation and the total number of procedures declined.<sup>14</sup>

Between 2006 and 2008, all racial groups except Asian Americans experienced a decrease in the rate of kidney transplantation. During that period, kidney transplants from living donors declined by 4 percent, while transplants from deceased donors declined by 1 percent (United States Renal Data System 2010). The text box summarizes issues related to the distribution of kidney transplantation across the ESRD population.

Overall rates of hospitalization remained steady at about two admissions per dialysis patient per year.

Between 2003 and 2008, conditions related to ESRD—cardiovascular conditions, infections, and vascular access complications—accounted for the majority of inpatient admissions for hemodialysis patients. In 2008, the most current year for which data are available, cardiovascular conditions accounted for nearly 30 percent of admissions for hemodialysis patients, infections accounted for 25 percent, and vascular access complications accounted for 13 percent (United States Renal Data System 2010). For peritoneal dialysis patients, between 2003 and 2008, the leading cause of admission was infections followed by cardiovascular conditions and access complications. In

2008, infections accounted for 34 percent of admissions, cardiovascular conditions accounted for 25 percent, and access complications accounted for 15 percent (United States Renal Data System 2010).

### **Dialysis quality by type of organization in 2008**

Data published by USRDS show that dialysis quality, as measured by standardized hospitalization and mortality rates, varies across types of dialysis organizations, including large dialysis chains, smaller dialysis chains, independent facilities, and hospital-based facilities.

In 2008, for all patients, small dialysis chains had slightly lower standardized hospitalization and mortality rates than large dialysis chains; independent facilities had higher standardized hospitalization rates. Although hospital-based facilities had lower hospitalization rates, they had the highest standardized mortality rates among the different facility types.

Outcomes by race varied between and within organizations. Some organizations had lower hospitalization and mortality rates for African Americans and higher ones for whites. By contrast, in hospital units, standardized hospitalization rates were lower for whites and higher for African Americans. The third largest dialysis chain in 2008 had the lowest standardized hospitalization and mortality rates for all patients as well as separately for whites and African Americans.

### **Providers' access to capital: Growth trends suggest access is adequate**

Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients requiring dialysis. Between 2008 and 2010, the large and small dialysis chains showed similar growth rates, which suggests that both small and large providers have adequate access to capital. During this period, the number of hemodialysis stations operated by the two largest organizations (Fresenius Medical Care North America and DaVita) grew by 6 percent; in comparison, the number of hemodialysis stations operated by smaller freestanding chains grew by an average of 4 percent.

The two large dialysis organizations as well as medium-sized companies appeared to have adequate access to capital in 2010. For example, in 2010, Fresenius acquired Gambro's peritoneal dialysis business and raised its acquisition spending guidance to \$500 million from \$400 million. DaVita signed a new \$3 billion secured credit

agreement, and Deutsche Bank concluded that there was a solid group of well-capitalized medium-sized dialysis organizations (Deutsche Bank 2010). In addition, at least six dialysis companies were owned by private equity groups (Deutsche Bank 2010). U.S. Renal Care raised \$25 million in new equity in 2010 to complete its acquisition of Dialysis Corporation of America, and a private equity firm acquired American Renal Associates.

The two largest dialysis organizations enjoyed mostly positive ratings from investor analysts in 2010, who have generally viewed dialysis providers' fundamentals—including the aging of the U.S. population, the higher incidence of diabetes, and recurring demand—and low sensitivity to economic cycles as favorable from an economic perspective. In addition, investor analysts remain favorable about the dialysis sector because of its record of solid growth rates and available "free cash flow," the cash flow available for distribution among an organization's securities holders. Both Fresenius and DaVita were included in the top 10 health care facility stocks with the highest cash flow per share between 2009 and 2010.

After considering the new payment method, investor analysts remain positive about the long-term economic prospects for the dialysis sector. For example, Deutsche Bank stated that "bundling could favorably alter the economics for dialysis providers over both a medium-term and long-term basis." A key point made by Deutsche Bank is that Medicare bundling should lead to greater efficiency, and that this change will come through a variety of means, including cost-effective utilization and mix of resource inputs (especially drugs and laboratory services) and a gradual shift over time toward home-based dialysis.

### **Medicare payments and providers' costs**

Each year, we assess freestanding providers' costs and the relationship between Medicare's payments and freestanding providers' costs by considering whether current costs approximate what efficient providers are expected to spend on delivering high-quality care. The latest and most complete data available on freestanding providers' costs are from 2009.

### **Appropriateness of current costs**

To assess the appropriateness of costs, we examine whether aggregate dialysis costs provide a reasonable representation of costs that efficient providers would incur in furnishing high-quality care. Between 2004 and 2009, the cost per treatment for composite rate services



rose by 3.2 percent per year. (This growth rate is the same rate we reported last year for the period 2003 to 2008 for freestanding facilities.) Variation in cost growth across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2004 and 2009, per treatment costs increased by 1.4 percent per year for facilities in the 25th percentile of cost growth, compared with 5.0 percent for facilities in the 75th percentile. The growth in cost per treatment during that period partly stems from rising general and administrative costs, which increased by 6 percent per year and accounted for nearly 30 percent of the total cost per treatment in 2009. General and administrative costs include expenses associated with legal and accounting services, record-keeping and data-processing tasks, telephone and other utilities, home office costs, and malpractice premiums. By contrast, between 2004 and 2009, capital and labor costs (associated with direct patient care) increased by 3 percent and 2 percent per year, respectively; other direct medical costs decreased by 0.2 percent per year. In 2009, capital, labor, and other direct medical costs accounted for 20 percent, 41 percent, and 11 percent, respectively, of the total cost per treatment. Cost report data do not permit us to assess which cost elements contribute to the high rate of cost growth within the general and administrative cost category.

### Medicare margin for freestanding providers

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 payments and costs are from 2009.

For 2009, we estimate that the aggregate Medicare margin for composite rate services and dialysis drugs was 3.1 percent. The distribution of margins in 2009 shows wide variation in performance among freestanding facilities. One-quarter of facilities had margins at or below -5.0 percent, but half the facilities had Medicare margins of at least 3.6 percent, and one-quarter of facilities had Medicare margins of at least 12.3 percent.

The aggregate margin of 3.1 percent in 2009 is relatively unchanged from the 2008 aggregate margin of 3.2 percent. Changes in drug cost and payment per treatment partly explain this direction. Between 2008 and 2009, drug payment per treatment increased by more than 5 percent while drug cost per treatment increased by 3 percent. As in earlier years, urban facilities had higher

**TABLE  
6-5**

### Medicare margin in 2009 varies by type of freestanding provider

Provider type	Percent of spending	Medicare margin
All	100%	3.1%
Affiliated with one of the two large dialysis organizations	69	4.4
All others	31	0.3
Urban	83	4.1
Rural	17	-1.4

Source: Compiled by MedPAC from 2009 cost report and outpatient claims submitted by facilities to CMS.

margins than rural facilities (4.1 percent vs. -1.4 percent, respectively), and facilities affiliated with the two largest dialysis organizations tended to have higher margins than other freestanding facilities (4.4 percent vs. 0.3 percent, respectively) (Table 6-5).

The Commission is concerned that the gap in the Medicare margin widened between urban and rural facilities between 2008 and 2009 (Medicare Payment Advisory Commission 2010b). We will continue to monitor the adequacy of Medicare's payments for rural and urban facilities in the upcoming years. As mentioned earlier, some rural facilities are expected to benefit from the low-volume adjustment that is included in the new payment method.

On the basis of 2009 payment and cost data, we project that the 2011 aggregate margin will be 1.3 percent. This estimate reflects:

- the 2 percent reduction in total spending that MIPPA mandated to begin in 2011,
- the 3.1 percent budget-neutrality payment reduction in 2011,
- the 2011 payment update of 2.5 percent, and
- a conservative behavioral offset to account for efficiencies anticipated under the new payment method.

The conservative behavioral offset included in the 2011 margin projection is based on reports that providers will become more efficient in the delivery of drug and laboratory tests. One investor predicted that use of erythropoietin will decrease by between 10 percent and

15 percent in 2011 (Wells Fargo Securities 2010). Another investor analyst predicted that erythropoietin use will decline by 20 percent between 2011 and 2014 (Deutsche Bank 2010). As mentioned earlier, an industry association reported that a substantially greater proportion of facilities have opted into the new payment method (about 90 percent) than CMS estimated (43 percent), suggesting that most facilities can operate within the provisions of the new payment method. Published studies also suggest that providers can decrease costs while maintaining quality (Hasegawa et al. 2010, Kaufman et al. 1998, Pizzi et al. 2006). Charytan summarized the following selected strategies to maximize efficiencies in the management of anemia: switching from intravenous to subcutaneous routes, lowering hemoglobin targets and doses in hyporesponsive patients, increasing administration of intravenous iron, increasing use of home dialysis, and optimizing ESA dosing intervals (Charytan 2010).

## How should Medicare payments change in 2012?

CMS measures price inflation for the goods and services associated with the composite rate. CMS's latest forecast of this index for calendar year 2012 is 2.9 percent.

### Update recommendation

The evidence on payment adequacy suggests that a moderate update of the composite rate is in order. Therefore, the Commission recommends that the Congress update the outpatient dialysis payment rate by 1 percent for calendar year 2012.

## RECOMMENDATION 6

**The Congress should update the outpatient dialysis payment rate by 1 percent for calendar year 2012.**

### RATIONALE 6

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. The Medicare margins in 2008 (3.2 percent) and 2009 (3.1 percent) remained constant.

### IMPLICATIONS 6

#### Spending

- This recommendation would decrease federal program spending relative to current law by less than \$50 million in 2012 and by less than \$1 billion over five years.

#### Beneficiary and provider

- We do not anticipate any negative effects on beneficiary access to care. This recommendation is not expected to affect providers' willingness or ability to serve beneficiaries.

Under current law, if current projections were used, the payment rate would be updated by the ESRD market basket less a productivity adjustment, an update of 1.6 percent. ■

## Endnotes

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- 1 To be eligible for Medicare ESRD benefits: (1) the individual must file an application for Medicare with Social Security; (2) a physician must certify that the individual requires chronic dialysis or a kidney transplant to maintain life; and (3) the individual must be entitled to a monthly benefit under Social Security, be fully or currently insured under Social Security, or be the spouse or dependent child of a person meeting these Social Security requirements. Individuals qualify for Social Security by earning Social Security credits when employed in a job that pays Social Security taxes. Generally, individuals are fully insured under Social Security if they have 40 credits of covered employment. Individuals are currently insured under Social Security if they have a minimum of 6 credits of covered employment in the three years before ESRD diagnosis (<http://www.ssa.gov/pubs/10072.html>). Individuals who are not eligible for Social Security have not earned a minimum number of credits toward retirement under Social Security.
- 2 New dialysis patients include those who are covered by Medicare and those who are not eligible for Medicare either because they do not meet the eligibility criteria (explained in Endnote 1) or because they have not yet applied for Medicare coverage.
- 3 Although some of these ESRD beneficiaries have a successful kidney transplant, we infer that an increasing proportion of them are on dialysis because: (1) the total number of dialysis patients grew by 4 percent per year between 2005 and 2008, while the total number of dialysis FFS beneficiaries grew by 1 percent per year; and (2) the proportion of all dialysis patients not covered by Medicare has remained constant during this time period.
- 4 Beneficiaries with ESRD on dialysis cannot join an MA plan unless they developed ESRD while already enrolled in an MA plan. Enrollment in an ESRD special needs plan or the ESRD demonstration program are exceptions to this statutory provision.
- 5 Clinical experts consider the glomerular filtration rate as the best measure of residual kidney function (National Kidney Foundation 2011). Lower values of this rate suggest reduced residual kidney function. Experts generally consider an estimated glomerular filtration rate of less than 15 milliliters (mL)/minute (min)/1.73 square meters (m<sup>2</sup>) as end-stage renal failure. Between 1995 and 2008, among newly treated dialysis patients, the estimated glomerular filtration rate increased by 3 percent according to the two methods used to calculate it (from 7.6 mL/min/1.73 m<sup>2</sup> to 11.1 mL/min/1.73 m<sup>2</sup> according to the Modification of Diet in Renal Disease equation and from 6.9 mL/min/1.73 m<sup>2</sup> to 10.5 mL/min/1.73 m<sup>2</sup> according to the Chronic Kidney Disease Epidemiology Collaboration equation) (United States Renal Data System 2010).
- 6 The MMA required that freestanding dialysis facilities' payments for dialysis drugs be based on their acquisition costs. Before the MMA, Medicare paid freestanding facilities a statutory rate for erythropoietin and 95 percent of the average wholesale price or a statutory rate for all other dialysis drugs.
- 7 CMS will award up to 10 points to each of the three quality measures. The scoring methodology will subtract 2 points from each measure's score for every 1 percentage point the facility's performance falls below the performance standard.
- 8 CMS provides annual Dialysis Facility Reports to facilities, ESRD Network Organizations, and state survey agencies that provide facility-specific and comparative information on patient characteristics, treatment patterns, hospitalizations, mortality, and transplantation patterns. In addition, the Dialysis Facility Reports contain practice patterns such as managing dose of dialysis, vascular access, and anemia.
- 9 Medicare's conditions for coverage are the requirements that dialysis facilities must meet to be certified under the Medicare program. In 2008, CMS issued a final rule updating dialysis facilities' conditions for coverage (Centers for Medicare & Medicaid Services 2008).
- 10 The Charlson index is a comorbidity scale in which a higher score means that more comorbidities are present. The mean Charlson index was 4.0 for facilities in business and closed facilities.
- 11 This analysis uses data from CMS's Dialysis Compare file to obtain street addresses for dialysis facilities and the Renal Management Information System file for beneficiaries' residence. Travel distances were calculated using the Environmental Systems Research Institute's ArcGIS and weighted based on the number of treatments the beneficiary received at the facility. Although not presented, we also found similar trends in travel distances for all dialysis FFS beneficiaries.
- 12 Two factors contributed to this slowdown. First, in March 2007, the FDA included a "black box warning" on ESA drug labels to advise physicians about ESA dosage adjustments: They should maintain the lowest hemoglobin level needed to avoid a blood transfusion. Hemoglobin indicates a patient's anemia status, measured as grams of hemoglobin per deciliter of blood (g/dL). The FDA added the warning based on evidence from recent studies showing that higher target hemoglobin values were associated with increased mortality and morbidity for patients with chronic kidney disease (who are not on dialysis) and for cancer patients. Second, in 2008,

CMS changed its national payment policy for ESAs based on the recent studies and the FDA warning about the risks associated with large doses of ESA and high hemoglobin levels. The policy change reduces payment for ESAs if providers do not reduce the dosage for a patient whose hemoglobin level exceeds 13 g/dL.

- 13 Physicians create an AV fistula by joining an artery to a vein under the patient's skin (frequently in the forearm). A few months are usually needed to allow the AV fistula to properly develop before it can be used during dialysis. Physicians may implant an AV graft for certain patients (including those with small or weak veins) who are not candidates for an AV fistula.

Like AV fistulas, AV grafts are implanted under the skin, usually in the patient's forearm. AV grafts use a soft plastic tube to join an artery and a vein. Compared with AV fistulas, AV grafts can be used sooner after placement, often within two to three weeks. A catheter placed in the patient's neck, chest, or leg is used as a temporary access when a patient needs dialysis immediately and is waiting for an AV fistula or AV graft to mature. A catheter is also used when an AV fistula or AV graft fails.

- 14 The number of kidney transplants declined from 18,059 in 2006 to 17,413 in 2008.

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