

CHAPTER

6

Outpatient dialysis services

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

- 6** The Congress should increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2017.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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(Additionally, the Commission reiterates its March 2014 recommendation for redesigning the low-volume payment adjustment and auditing dialysis facilities' cost reports. See text box, p. 167.)

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2014, about 383,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 6,300 dialysis facilities. Since 2011, Medicare has paid for outpatient dialysis services using a prospective payment system (PPS) that is based on a bundle of services that includes certain dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2014, Medicare expenditures for outpatient dialysis services were \$11.2 billion, a 1 percent increase compared with 2013 Medicare dialysis expenditures.

Assessment of payment adequacy

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

Beneficiaries' access to care—Measures of the capacity and supply of providers, beneficiaries' ability to obtain care, and changes in the volume of services suggest payments are adequate.

- **Capacity and supply of providers**—Dialysis facilities appear to have the capacity to meet demand. Growth in the number of dialysis treatment stations has kept pace with growth in the number of dialysis beneficiaries.

In this chapter

- Are Medicare payments adequate in 2016?
- How should Medicare payments change in 2017?
- Regulatory improvements to the dialysis PPS

- **Volume of services**—Between 2013 and 2014, the number of FFS dialysis beneficiaries and dialysis treatments each grew by 2 percent. At the same time, the per treatment use of most dialysis injectable drugs (including erythropoietin, which is used in anemia management) continued to decline, but at a slower rate than during the initial years of the PPS (2011 and 2012). The dialysis PPS created an incentive for providers to be more judicious about their provision of dialysis drugs.

Quality of care—Using CMS data, we looked at changes in quality indicators between 2010 and 2014. Rates of emergency department use modestly increased, while rates of mortality and hospitalization declined. With regard to anemia management, negative cardiovascular outcomes associated with high erythropoiesis-stimulating agent use have declined. Beneficiaries’ use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 8 percent to 10 percent of dialysis beneficiaries. However, home dialysis growth slowed between September 2014 and the first three months of 2015 because of a shortage of the solutions needed for the predominant home method, peritoneal dialysis.

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—Our analysis of Medicare payments and costs is based on 2013 and 2014 claims and cost report data submitted to CMS by freestanding dialysis facilities. During this period, cost per treatment increased by 1 percent, while Medicare payment per treatment decreased by about 1 percent (accounting for the sequester). Taking into account the sequester, we estimate that the aggregate Medicare margin was 2.1 percent in 2014, and the rate of marginal profit—that is, the rate at which Medicare payments exceed providers’ marginal cost—was nearly 18 percent. The 2016 Medicare margin is projected at 0.8 percent. The evidence suggests that payments are adequate; the Commission recommends that the Congress increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2017.

Concerns about Medicare’s PPS to pay for dialysis services

The Commission continues to have two concerns about the dialysis PPS:

- The low-volume payment adjustment does not sufficiently target facilities that are both low volume and isolated. Consequently, some facilities that receive this payment adjustment are in close proximity to other facilities. Only low-volume

facilities that are necessary to maintain access—those located in isolated areas—should receive enhanced payment.

- CMS has not yet examined the appropriateness of the costs that facilities include in their cost reports, which could be determined through cost report audits, and has used unaudited data to refine the ESRD market basket and the PPS payment adjustment factors. If facilities' costs are overstated, the Medicare margin—which the Commission uses as an indicator of payment adequacy—will be understated. Historically, some facilities have overstated costs on their cost reports. Auditing dialysis facilities' cost reports is necessary for good fiscal management.

To address these concerns, the Commission reiterates its March 2014 recommendation applicable to redesigning the low-volume payment adjustment and auditing dialysis facilities' cost report data. ■

Dialysis treatment choices

Dialysis replaces the filtering function of the kidneys when they fail. The two types of dialysis—hemodialysis and peritoneal dialysis (PD)—remove waste products from the bloodstream differently. Within these two types of dialysis, patients may select various protocols.

Most dialysis patients travel to a treatment facility to undergo hemodialysis three times per week, although patients can also undergo hemodialysis at home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Because of recent clinical findings, there is increased interest in more frequent hemodialysis, administered five or more times per week while the patient sleeps, and short (two to three hours per treatment) daily dialysis administered during the day. New research also has increased interest in the use of “every-other-day” hemodialysis; reducing the two-day gap in thrice-weekly hemodialysis could be linked to improved outcomes. See online Appendix 6-A to the Commission's March 2013 report for more discussion of the use of more frequent hemodialysis and home dialysis (available at http://www.medpac.gov/documents/reports/mar13_ch06_appendix.pdf?sfvrsn=0).

PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed independently in the patient's home or workplace five to seven days a week. During treatments, a chemical solution (dialysate) is infused into the patient's abdomen through a catheter. This infusion process (an exchange) is done either manually (continuous ambulatory peritoneal dialysis) or using a machine (continuous cycler-assisted peritoneal dialysis).

Each dialysis method has advantages and disadvantages—no one method is best for everyone. People choose a particular dialysis method for many reasons, including quality of life, patients' awareness of different treatment methods and personal preferences, and physician training and recommendations. The use of home dialysis has grown modestly since 2009, a trend that has continued under the dialysis prospective payment system. Some patients switch methods when their conditions or needs change. Although most patients still undergo in-center dialysis, home dialysis remains a viable option for many patients because of advantages such as increased patient satisfaction, better health-related quality of life, and fewer transportation challenges compared with in-center dialysis. ■

Background

End-stage renal disease (ESRD) is the last stage of chronic kidney disease and is characterized by permanent, irreversible kidney failure. Patients with ESRD 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 the variation in patients' suitability for transplantation, about 70 percent of ESRD patients undergo maintenance dialysis (see text box on dialysis treatment choices). 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.¹

In 2014, about 383,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and

received dialysis from nearly 6,300 dialysis facilities.² Since 2011, Medicare has been paying facilities using a prospective payment system (PPS) payment bundle that includes dialysis drugs (for which facilities previously received separate payments) and services for which other Medicare providers (such as clinical laboratories) previously received separate payments. In 2014, Medicare Part B expenditures for outpatient dialysis services included in the payment bundle were \$11.2 billion. In addition, Part D payments for dialysis drugs—calcimimetics and phosphate binders—that are not yet included in the PPS payment bundle totaled \$1.3 billion in 2013 (the most recent data available).

Characteristics of fee-for-service dialysis beneficiaries, 2014

Although Medicare generally does not provide disease-specific entitlement, the 1972 amendments to the Social Security Act extended Medicare benefits to people with

**TABLE
6-1**

FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2014

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
Age		
Under 45 years	12%	4%
45–64 years	38	13
65–74 years	26	47
75–84 years	18	23
85+ years	6	12
Sex		
Male	55	46
Female	45	54
Race		
White	48	81
African American	36	10
All others	16	8
Residence, by type of county		
Urban	82	78
Rural micropolitan	11	13
Rural, adjacent to urban	5	6
Rural, not adjacent to urban	2	4
Frontier	1	1

Note: FFS (fee-for-service). Urban counties contain a cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, and rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

Source: Data compiled by MedPAC from 2014 claims submitted by dialysis facilities to CMS and the 2014 CMS denominator file.

ESRD, including those under age 65. To qualify for the ESRD program, an individual must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits (i.e., has met the required work credits) under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary.

Most dialysis beneficiaries have FFS coverage. The statute prohibits enrollment of individuals with ESRD in

Medicare Advantage (MA) plans. However, beneficiaries who were enrolled in a managed care plan before an ESRD diagnosis can remain in the plan after they are diagnosed. In addition, CMS permits the enrollment of ESRD beneficiaries with a functioning kidney transplant in MA. In 2014, about 15 percent of ESRD beneficiaries were enrolled in MA plans; by comparison, about 30 percent of all Medicare beneficiaries were enrolled in MA plans. In 2000, the Commission recommended that the Congress lift the prohibition on ESRD beneficiaries enrolling in MA (Medicare Payment Advisory Commission 2000).

In 2014, a majority (nearly 90 percent) of FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage. In 2014, about 70 percent of FFS dialysis beneficiaries with Part D coverage received the low-income subsidy, and about 11 percent of FFS dialysis beneficiaries in 2014 had either no Part D coverage or coverage less generous than Part D’s standard benefit.

Compared with all Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately young, male, and African American, and they are more likely to reside in urban areas (Table 6-1). In 2014, 76 percent of FFS dialysis beneficiaries were less than 75 years old, 55 percent were male, and 36 percent were African American. By comparison, of all FFS Medicare beneficiaries, 65 percent were less than 75 years old, 46 percent were male, and 10 percent were African American. A greater share of dialysis beneficiaries reside in urban areas compared with all FFS beneficiaries (82 percent vs. 78 percent, respectively). In 2014, FFS dialysis beneficiaries were more likely to be dually eligible for Medicaid and Medicare, compared with all Medicare FFS beneficiaries (48 percent vs. 19 percent, respectively; data not shown).

Between 2003 and 2013 (most recent data available), the adjusted rate (or incidence) of new ESRD cases (which includes patients of all types of health coverage who initiate dialysis or receive a kidney transplant) decreased by 1 percent per year, from 386 per million people to 351 per million people (United States Renal Data System 2015). Between 2009 and 2013, the adjusted rate declined across all races and ethnicities (White, African American, Asian Americans, Native American, and Hispanic) and all age groups; overall, the decrease averaged 2 percent per year.³ In 2014, we estimate that approximately 82,000 FFS dialysis beneficiaries were new to dialysis, and nearly

half (45 percent) were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).⁴

Better primary care management of the risk factors for kidney disease—particularly hypertension and diabetes, which together are the primary cause of 7 of 10 new ESRD cases—can help prevent or delay the illness’s onset (United States Renal Data System 2015). Although risk-factor control for hypertension and diabetes has improved for all racial and ethnic groups in Medicare, disparities remain between African Americans and other racial groups. The Commission has long argued that primary care providers are undervalued in Medicare’s fee schedule and has made recommendations to support primary care, which in turn could support better management of kidney disease risk factors.

Since 2011, CMS pays for dialysis services under the dialysis PPS

To treat ESRD, dialysis beneficiaries receive care from two principal providers: (1) the clinicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary’s plan of care and (2) facilities that provide dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Medicare uses different methods to pay for ESRD clinician and facility services. Clinicians receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis-related management services, which varies based on the number of visits per month, the beneficiary’s age, and whether the beneficiary receives dialysis in a facility or at home. While this report section focuses on Medicare’s payments to facilities, it is important to recognize that facilities and clinicians collaborate to care for dialysis beneficiaries. One acknowledgment of the need for collaboration is Medicare’s Comprehensive ESRD Care Initiative, a shared savings program involving facilities and nephrologists that began in 2015.

To improve provider efficiency, in 2011, Medicare began a PPS for outpatient dialysis services that expanded the payment bundle to include dialysis drugs, laboratory tests, and other ESRD items and services that were previously separately billable. In addition, effective 2012, outpatient dialysis payments are linked to the quality of care that dialysis facilities provide. These changes, mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), were based on the Commission’s recommendation to modernize the outpatient dialysis

payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for the efficient delivery of quality care by broadening the payment bundle (to include commonly furnished drugs and services that providers formerly billed separately) and by linking payment to quality. The PPS is designed to create incentives for facilities to provide services more efficiently by reducing previous incentives inherent in the former payment method to overuse drugs.

Under the outpatient dialysis PPS, the unit of payment is a single dialysis treatment. In 2015, the base payment rate was adjusted for patient-level characteristics (age, body measurement characteristics, onset of dialysis, and selected acute and chronic comorbidities) and facility-level factors (low treatment volume and local input prices).⁵ Medicare pays facilities furnishing dialysis treatments in-facility or in a patient’s home for up to three treatments per week, unless there is documented medical justification for more than three weekly treatments. In addition, in 2015, the ESRD Quality Incentive Program held facilities responsible for the quality of care they provided, using six clinical measures and four reporting measures. Up to 2 percent of a facility’s payment is linked to these quality measures. The Commission’s *Payment Basics* provides more information about Medicare’s method of paying for outpatient dialysis services (available at <http://medpac.gov/documents/payment-basics/outpatient-dialysis-services-payment-system-15.pdf?sfvrsn=0>).

Since its implementation in 2011, the dialysis PPS has undergone two significant changes. First, effective 2014, the base payment rate was rebased to account for the decline in dialysis drug use under the dialysis PPS. Based on statutory and regulatory changes, CMS set the 2014 base payment at \$239.02. The Commission’s March 2014 report to the Congress provides more information about the rebasing of the dialysis base payment rate (http://medpac.gov/documents/reports/mar14_ch06.pdf?sfvrsn=0).

Second, beginning in 2016, CMS uses recalibrated and redefined patient-level and facility-level payment adjustments to calculate each patient’s adjusted payment per treatment. These adjusters are applied to the base payment rate to account for factors that may affect treatment costs. Table 6-2 (p. 154) compares the payment adjusters implemented in 2011 and 2016, and a text box (p. 154) summarizes the changes to the dialysis PPS that began in 2016.

Beginning in 2016, the dialysis PPS uses refined payment adjusters

The American Taxpayer Relief Act of 2012 required that the Secretary, no later than January 1, 2016, analyze the case-mix payment adjustments that are applied to the base rate under the current dialysis prospective payment system (PPS) and make appropriate revisions to the adjustments. Through the rule-making process, CMS proposed and finalized recalibrated patient- and facility-level payment adjustment factors based on regression analyses of 2012 and 2013 dialysis facilities' cost reports and claims data (Table 6-2). Beginning in 2016, CMS uses the recalibrated payment adjusters to calculate each patient's adjusted payment rate; other major changes to the dialysis PPS that have begun in 2016 are:

- the removal of two comorbidity payment adjustment factors (bacterial pneumonia and monoclonal gammopathy) because of differences in diagnostic and medical documentation requirements;

- the use of a new rural payment adjuster that is applied to all facilities not located in urban areas. Medicare defines urban areas as a metropolitan statistical area or a metropolitan division; and
- the use of a revised definition of the low-volume payment adjuster.

In our comment letter to CMS on the dialysis PPS changes that CMS implemented in 2016, the Commission raised several methodological concerns about the refinements, including the specification of the regression model and the patient-level adjusters. The Commission's comment letter provides more information about our methodological concerns with the 2016 PPS (available at <http://medpac.gov/documents/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-quality-incentive-program.pdf?sfvrsn=0>). ■

**TABLE
6-2**

Payment adjustment factors for the dialysis PPS implemented in 2011 and 2016

Payment adjuster	Value of payment adjusters	
	Implemented in CY 2011	Implemented in CY 2016
Age		
18–44 years	1.171	1.257
45–59 years	1.013	1.068
60–69 years	1.000	1.070
70–79 years	1.011	1.000
80+ years	1.016	1.109
Body surface area (per 0.1 m ²)	1.020	1.032
Underweight (body mass index < 18.5 kg/m ²)	1.025	1.017
Time since onset of dialysis (<4 months)	1.510	1.327
Comorbidities		
Pericarditis	1.114	1.040
Gastrointestinal tract bleeding	1.183	1.082
Bacterial pneumonia	1.135	—
Hereditary hemolytic/sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	—
Facility low-volume status	1.189	1.239
Facility rural status	—	1.008

Note: PPS (prospective payment system), CY (calendar year). Payment adjustment factors are for ages 18 and older. Dashes denote that factor was not used to adjust payment.

Source: Center for Medicare & Medicaid Services 2015.

Are Medicare payments adequate in 2016?

To address whether payments for 2016 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2017), we examine several indicators of payment adequacy. We assess beneficiaries' access by examining the capacity of dialysis facilities 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 facilities' costs. Most of our payment adequacy indicators for dialysis services are positive:

- Provider capacity is sufficient.
- Volume growth as measured by the number of dialysis treatments has kept pace with growth in the number of beneficiaries.
- Some quality measures show improvement, while others need improvement.
- Provider access to capital is sufficient.
- The 2014 Medicare outpatient dialysis margin is estimated at 2.1 percent, and the rate of marginal profit is nearly 18 percent.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand and changes in the volume of services—shows that beneficiaries' access to care remains favorable.

Capacity has kept pace with patient demand

Growth in the number of dialysis facilities and treatment stations alongside growth in dialysis beneficiaries suggests that between 2009 and 2014, provider capacity kept up with demand for care. During that period, the number of facilities increased annually by 3 percent; facilities' capacity to provide care—as measured by dialysis treatment stations—also grew 3 percent annually (Table 6-3, p. 156). By contrast, between 2009 and 2014, the number of beneficiaries grew 2 percent annually (data not shown). Capacity at facilities that were freestanding and for profit each grew by 4 percent annually while capacity at facilities that were hospital based and nonprofit decreased annually (–5 percent and –2 percent,

respectively). Capacity at urban facilities grew at 3 percent per year while capacity at rural facilities grew at 2 percent per year. Dialysis capacity between 2013 and 2014 grew modestly faster, on average, relative to 2009 to 2014.

Providers of outpatient dialysis services

In 2014, there were roughly 6,300 dialysis facilities in the United States. Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2014, freestanding facilities furnished 94 percent of FFS treatments, and for-profit facilities furnished about 90 percent (Table 6-3, p. 156). In 2014, the capacity of facilities located in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations (LDOs) dominate the dialysis industry. In 2014, these two LDOs accounted for about 71 percent of all facilities and 75 percent of all Medicare treatments. In addition to operating most dialysis facilities, the two LDOs are each vertically integrated. One manufactures and distributes renal-related pharmaceutical products (e.g., phosphate binders), is the leading supplier of dialysis products (such as hemodialysis machines and dialyzers) to other dialysis companies, and operates a drug and device clinical development company that focuses on the clinical development of new renal therapies. Both organizations operate an ESRD-related laboratory, a pharmacy, and one or more centers that provide vascular access services; they provide ESRD-related disease management services; and they operate dialysis facilities internationally. Both organizations have, in recent years, acquired physician and hospital groups.

Together, both LDOs have grown faster after the PPS's implementation than before the PPS. Between 2011 and 2014, the total number of facilities operated by the LDOs grew in aggregate by about 21 percent. By comparison, before the PPS, between 2008 and 2011, the two LDOs grew in aggregate by about 18 percent.

Type of facilities that closed and their effect on beneficiaries' access to care

Each year, we assess the type of facilities that closed and whether certain groups of Medicare dialysis beneficiaries are disproportionately affected by facility closures. Using facilities' claims submitted to CMS and CMS's Dialysis Compare database and Provider of Services file, we compared the characteristics of beneficiaries treated by facilities that closed in 2013 with those treated by facilities

**TABLE
6-3**

Increasing number and capacity of freestanding, for-profit, and large dialysis organizations

	2014				Average annual percent change			
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities		Number of stations	
					2009-2013	2013-2014	2009-2013	2013-2014
All	44.9	6,300	110,700	18	3%	5%	3%	4%
	Percent of total							
Freestanding	94%	93%	94%	18	4	6	4	5
Hospital based	6	7	6	14	-5	-5	-5	-6
Urban	85	80	83	18	3	5	3	4
Rural, micropolitan	11	13	11	16	1	3	2	2
Rural, adjacent to urban	3	5	4	13	2	0	3	1
Rural, not adjacent to urban	1	3	2	12	1	3	2	3
Frontier	0.2	0.6	0.4	11	-1	6	3	6
For profit	90	87	88	18	4	6	4	5
Nonprofit	10	13	12	17	-3	-2	-2	-1
Two largest dialysis organizations	75	71	73	18	6	5	7	4
All others	25	29	27	17	-4	4	-4	3

Note: FFS (fee-for-service). Urban counties contain a cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, and rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from the 2009, 2013, and 2014 Dialysis Compare database from CMS and 2014 claims submitted by freestanding and hospital-based dialysis facilities to CMS.

that provided dialysis in 2013 and 2014, the most current years for which complete data are available.

Between 2013 and 2014, the number of dialysis treatment stations—a measure of providers’ capacity—increased by 4 percent (Table 6-3). Compared with facilities that treated beneficiaries in both years, facilities that closed in 2013 (about 40 facilities) were more likely to be hospital based, nonprofit, and smaller (as measured by the number of dialysis treatment stations), which is consistent with long-term trends in supply of dialysis providers.

Few dialysis beneficiaries (about 2,300 individuals) were affected by facility closures in 2013. Our analysis found that beneficiary groups who were disproportionately

affected included beneficiaries who were White and older. Our analysis of claims data suggests that beneficiaries affected by these closures obtained care elsewhere.

Volume of services

To assess changes in the volume of dialysis services, we examined recent trends in the number of dialysis treatments provided to beneficiaries and in the use of injectable drugs administered during dialysis.

Trends in number of dialysis treatments provided

Between 2013 and 2014, total dialysis treatments grew at an average annual rate that kept pace with the average annual growth in the number of total FFS dialysis beneficiaries—2 percent per year. During this period,

**TABLE
6-4**

Use per treatment of dialysis drugs has declined under the outpatient dialysis PPS

Dialysis drug	Mean units per treatment*			Aggregate percent change		
	2007	2010	2014	2007-2010	2010-2013	2013-2014
ESAs						
Erythropoietin	5,532	5,214	2,860	-6%	-44%	-2%
Darbepoetin alfa	1.52	1.26	0.75	-17	-55	33
Iron agents						
Sodium ferric gluconate	0.39	0.15	0.12	-62	-3	-14
Iron sucrose	12.3	16.0	12.9	30	-21	3
Ferumoxytol	N/A**	0.8	0.02	N/A**	-97	-29
Vitamin D agents						
Paricalcitol	2.3	2.3	0.4	-2	-40	-72
Doxercalciferol	0.8	0.9	1.9	8	38	59
Calcitriol	0.16	0.13	0.03	-17	-63	-29
Antibiotics						
Daptomycin	0.097	0.217	0.144	123	-29	-7
Vancomycin	0.029	0.024	0.017	-18	-22	-12
Other drugs						
Levocarnitine	0.017	0.010	0.003	-43	-68	-12
Alteplase	0.023	0.020	0.003	-12	-85	-17

Note: PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not available). Individual units per treatment are rounded; the aggregate percent change is calculated using unrounded units per treatment.

*Each drug is reported using its own drug units.

**Drug use not available because drug was not marketed in the United States in 2007, 2008, and 2009.

Source: MedPAC and Acumen analysis of 2007-2014 claims submitted by dialysis facilities to CMS.

the non-annualized number of dialysis treatments per beneficiary has remained steady at about 117 treatments.

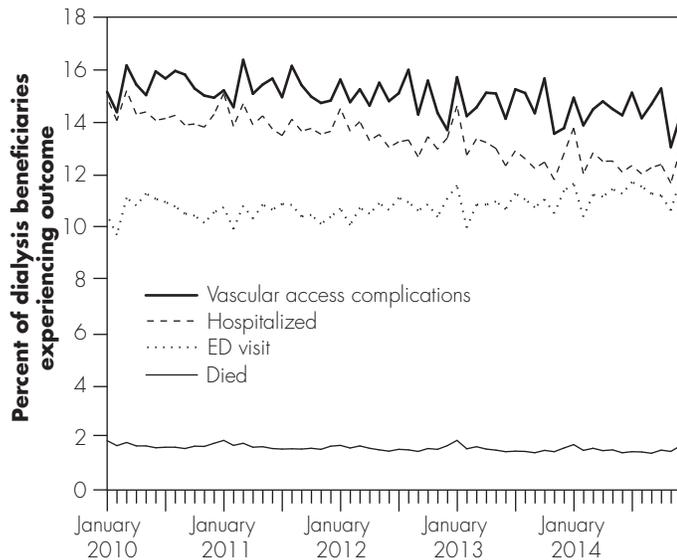
Use of most dialysis drugs has declined under the outpatient dialysis PPS Because CMS based the bundled payment rate in the dialysis PPS on a per treatment basis and on 2007 utilization data, we examined changes between 2007 and 2014 (the most current year for which complete data are available) in the use per treatment for the leading 12 dialysis drugs and aggregated them into 4 therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics.⁶ We also examined changes in the use of drugs between 2010 (the year before the start of the PPS) and 2013 and between 2013 and 2014.

The dialysis PPS increased the incentive for providers to be more judicious in providing dialysis drugs since those drugs are included in the payment bundle. Under the prior

payment method, dialysis drugs were paid according to the number of units of the drug administered—in other words, the more units of a drug provided, the higher the Medicare payment.

Between 2007 and 2014, the use of most dialysis drugs declined. During this period, use of eight drugs declined while three increased (ferumoxytol was not marketed in the United States in 2007) (Table 6-4). Between 2007 and 2014, the per treatment dose of both ESAs declined—erythropoietin by 48 percent and darbepoetin alfa by 50 percent.

However, most of the decline in the use of dialysis drugs has occurred under the PPS. For example, between 2010 and 2014, the mean per treatment units of both ESAs declined—erythropoietin by 45 percent and darbepoetin alfa by 40 percent. For ESAs, some of this decline may also have stemmed from clinical evidence showing that higher doses of these drugs led to increased risk of

FIGURE 6-1**Changes in key outcomes for dialysis beneficiaries, 2010–2014**

Note: ED (emergency department). Data are compiled on a monthly basis by CMS.

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2014 claims-based monitoring program.

morbidity and mortality, which resulted in the Food and Drug Administration changing the ESA label in 2011.

Between 2013 and 2014, the use of most dialysis drugs continued to decline but at a lower rate than during the initial years of the PPS. The per treatment use of three drugs increased between 2013 and 2014: Use of darbepoetin alfa, an ESA, increased by 33 percent (from 0.56 mcg to 0.75 mcg per treatment); use of iron sucrose increased by 3 percent (from 12.55 mg to 12.90 mg per treatment); and use of doxercalciferol, a vitamin D agent, increased by 59 percent (from 1.2 mcg to 1.9 mcg per treatment) (Table 6-4, p. 157; 2013 data not shown).

Under the PPS, drug utilization and average sales price (ASP) data suggest increased competition between the two principal vitamin D agents, which are both in the PPS payment bundle. Between 2010 and 2014, per treatment use of paricalcitol, the more costly vitamin D drug (according to Medicare ASP data), declined while per treatment use of doxercalciferol, the less costly vitamin D drug, increased (Table 6-4, p. 157). Between 2010 and 2015 (the latest year pricing data are available), the ASP

price per unit for both of these two products declined by 60 percent. By contrast, for all drugs in the bundle, the price per unit increased by about 15 percent during this period.⁷

Quality of care

This year's quality analysis focuses on changes in quality indicators since CMS implemented the PPS in 2011 and, except where indicated, uses CMS's monthly monitoring data (Centers for Medicare & Medicaid Services 2014). From 2010 to 2014, monthly mortality and hospitalization rates modestly declined; emergency department (ED) use remained relatively unchanged. Regarding anemia management, negative cardiovascular outcomes associated with high ESA use generally declined. During this period, use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased modestly. However, home dialysis growth slowed between 2014 and the first three months of 2015 because of a shortage of the solutions needed for the predominant home method, peritoneal dialysis (PD).

In assessing quality, we also examine the multiple factors that affect access to kidney transplantation. This procedure is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality of life outcomes, and demand far outstrips supply. We also discuss CMS's new payment model, which aims to improve the health outcomes of dialysis beneficiaries while lowering the total Medicare Part A and Part B per capita spending on these beneficiaries. Last, we discuss CMS's two quality measurement systems, the ESRD Quality Incentive Program (QIP) and the Dialysis Star Ratings Systems.

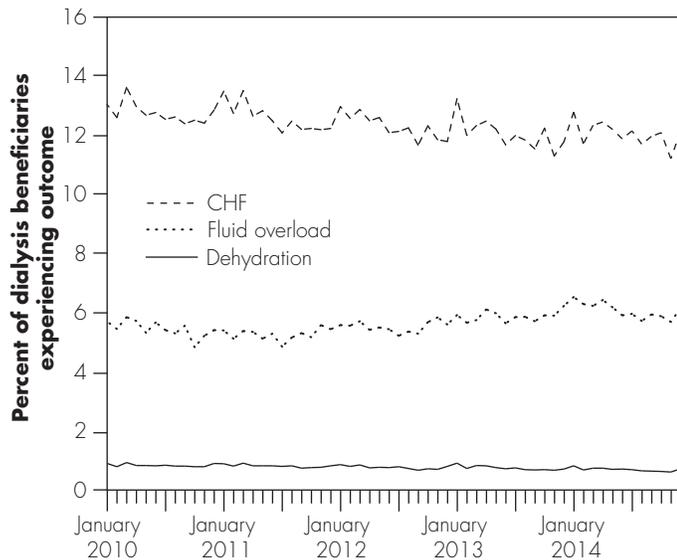
Quality under the PPS

Figure 6-1 presents changes in key patient outcomes between 2010 and 2014; during this period, the proportion of dialysis beneficiaries who:

- died declined from an average of 1.7 percent per month to 1.5 percent per month.
- used the ED increased modestly from an average of 10.7 percent per month to 11.3 percent per month.
- were hospitalized declined each year from an average of 14.3 percent per month to 12.5 percent. This finding is consistent with the trend of declining inpatient admissions for all Medicare FFS beneficiaries during this period.

FIGURE 6-2

Changes in fluid management, 2010–2014



Note: CHF (congestive heart failure). Data are compiled on a monthly basis by CMS.

Source: CMS’s end-stage renal disease prospective payment system overview of 2010–2014 claims-based monitoring program.

- experienced a vascular access complication on hemodialysis declined each year from an average of 15.4 percent to 14.4 percent per month.

Beneficiaries’ fluid management is related to factors such as the adequacy of the dialysis procedure and patient compliance. Figure 6-2 shows that, between 2010 and 2014, the share of dialysis beneficiaries diagnosed with congestive heart failure or dehydration declined slightly while the share of beneficiaries diagnosed with fluid overload increased slightly.

Process and health outcome measures reflect the change in anemia management under the PPS. From 2010 to 2014:

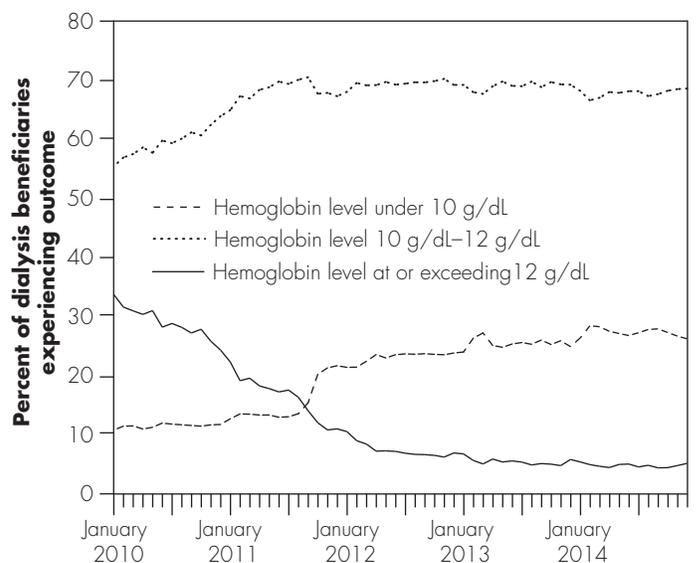
- Median monthly hemoglobin levels fell from 11.4 g/dl to 10.5 g/dL.⁸ According to the Commission’s analysis, the proportion of dialysis beneficiaries with higher hemoglobin levels declined, and the proportion with lower hemoglobin levels increased (which is generally associated with lower ESA use) (Figure 6-3).

- The proportion of beneficiaries receiving blood transfusions increased from 2.7 percent to 3.4 percent per month in 2012 and then decreased to 3.0 percent per month.⁹
- The cumulative share of beneficiaries experiencing negative cardiovascular outcomes—stroke, acute myocardial infarction, and heart failure—associated with higher ESA use generally declined.

As discussed in our June 2014 report, clinical process measures (such as hemoglobin levels) may exacerbate the incentives in FFS to overprovide and overuse services, including overuse of ESAs before the PPS was implemented in 2011 (Medicare Payment Advisory Commission 2014b). In addition, some clinical process measures may be only weakly correlated with better health outcomes. A given hemoglobin level may reflect adequate anemia management for one patient, whereas the same level may lead to a different response in a different patient. Focusing on clinical outcomes, such as rates of stroke, is a better indicator of anemia management in the dialysis population. The Commission believes that Medicare should transition over the next decade to a quality-measurement system that uses a small number of population-based outcome measures.

FIGURE 6-3

Changes in hemoglobin levels, 2010–2014

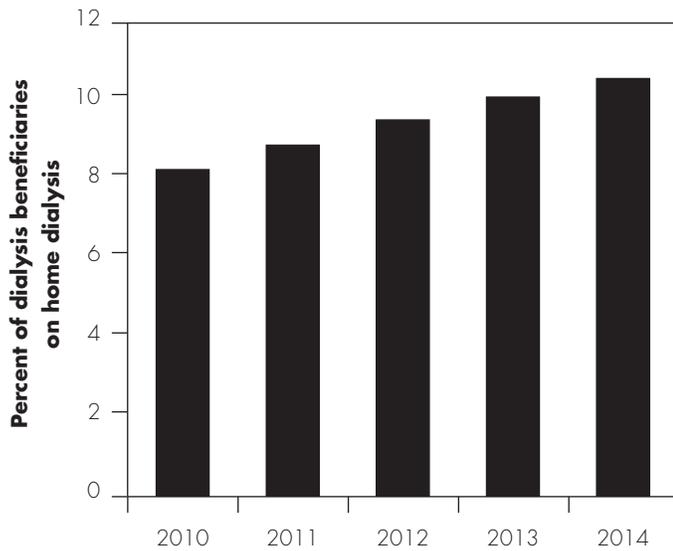


Note: Data are compiled on a monthly basis.

Source: MedPAC analysis of 2010–2014 claims submitted by dialysis facilities.

**FIGURE
6-4**

**Increasing use of home
dialysis, 2010–2014**



Note: Data represent yearly averages of data compiled by CMS on a monthly basis.

Source: CMS's end-stage renal disease prospective payment system overview of 2010–2014 claims-based monitoring program.

Under the dialysis PPS, adverse outcomes associated with bone and mineral disease management remain relatively rare. From 2010 to 2014, the proportion of beneficiaries experiencing a fracture or peptic ulcer disease remained steady at 2.1 percent and 0.02 percent per month, respectively, and the proportion of beneficiaries experiencing a kidney stone increased modestly from 0.39 percent to 0.45 percent per month.

Figure 6-4 shows that from 2010 through 2014, the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.3 percent to 10.6 percent, respectively. While we are encouraged by this modest increase, we are concerned that differences by race persist: African Americans are less likely to use home methods. According to the Commission's analysis, African Americans account for about 25 percent of home dialysis beneficiaries while they account for about 36 percent of all dialysis beneficiaries (data not shown).

Beginning September 2014, the growth in PD, the predominant home method, may have slowed because of a shortage of solutions needed to perform this type of dialysis.¹⁰ The proportion of beneficiaries dialyzing

at home peaked at 10.7 percent of dialysis beneficiaries between July and September 2014 and then declined to 10.3 percent in March 2015 (the most recent data available) (Centers for Medicare & Medicaid Services 2014). The supply shortage results from the product's leading manufacturer (Baxter) experiencing increased PD demand and limited manufacturing capacity (Baxter 2014, Neumann 2014).

Because of the shortage, beginning in August 2014, the manufacturer gave each dialysis provider an allocation for how many new patients could be started on PD based on the provider's history of growth during the first six months of 2014 (Seaborg 2015).¹¹ Although steps have been taken to increase the supply of PD solutions, the limitation on the number of new PD patients was maintained through the end of 2015.¹²

Access to kidney transplantation

Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality of life outcomes. However, demand for kidney transplantation exceeds supply. Factors that affect access to kidney transplantation include the clinical allocation process and donation rates; patients' health literacy, clinical characteristics, and preferences; the availability of patient educational efforts; clinician referral for transplant evaluation at a transplant center; and transplant center policies.

African Americans are less likely than Whites to receive kidney transplants despite their threefold greater likelihood of developing ESRD. According to Ephraim and colleagues (2012), the lower rates of kidney transplantation for African Americans are associated with multiple factors, including immunological incompatibility with deceased donor kidneys; lower rates of referral for transplantation; lower rates of cadaver kidney donation; and lack of knowledge and suboptimal discussions about kidney transplantation among recipients, their families, and health care providers (Ephraim et al. 2012).

In 2010, to help inform beneficiaries diagnosed with Stage IV chronic kidney disease (CKD) (the disease stage before ESRD) about managing CKD and related comorbidities and their options for care, MIPPA established Medicare payment of up to six sessions of kidney disease education (KDE) per beneficiary. Fewer beneficiaries were provided KDE services in 2014 than between 2011 and 2013—about 2,900 beneficiaries in 2014 compared with

about 4,200 beneficiaries in 2011 and 2012 and 3,600 beneficiaries in 2013. Medicare KDE spending in 2014 was about \$400,000.¹³

According to the Government Accountability Office, payment limitations on the providers who can furnish KDE services and the beneficiaries who are eligible might constrain the services' use (Government Accountability Office 2015). MIPPA specified the categories of providers who can furnish KDE services—physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certain providers of services located in rural areas.¹⁴ MIPPA also specified that beneficiaries with Stage IV CKD are eligible for the benefit. Some stakeholders contend that other categories of beneficiaries, including those with Stage V ESRD but who have not started dialysis, might also benefit from Medicare coverage.

The ESRD Comprehensive Care Initiative

The relatively high resource use of dialysis beneficiaries, particularly rates of hospital admissions and hospital readmissions, suggests that further improvements in quality are needed and that some dialysis beneficiaries might benefit from better care coordination. In online Appendix 6-A, available at <http://www.medpac.gov>, we present dialysis beneficiaries' resource use for all Part A and Part B services in 2013. Under the authority of the Center for Medicare and Medicaid Innovation, the Comprehensive ESRD Care Initiative began October 1, 2015, and is testing whether a new payment model implemented in FFS Medicare can improve the outcomes of dialysis beneficiaries as well as lower their Medicare per capita spending.

Under this five-year initiative, ESRD Seamless Care Organizations (ESCOs), which consist of at least one dialysis facility and one nephrologist, will be held accountable for the clinical and financial (Part A and Part B) outcomes of prospectively matched dialysis beneficiaries. Of the 13 participating ESCOs, 12 are operated by 3 large dialysis organizations (Dialysis Clinic Inc., DaVita, and Fresenius), which CMS defines as organizations that operate more than 200 dialysis facilities, and one ESCO is operated by a small dialysis organization (Rogosin Institute), defined as one that operates less than 200 dialysis facilities.

The ESCOs operated by the three large dialysis organizations are held to two-sided risk-based payment, while the one small dialysis organization is held to one-sided risk-based payment. The initial agreement period

lasts for three years; thereafter, CMS and each ESCO has the option of extending the agreement for an additional two years based on the ESCO's performance. Selected features of the model include:

- **Attribution:** CMS will prospectively match eligible dialysis beneficiaries to an ESCO through a claims-based process based on first touch, meaning that a beneficiary's first visit to a facility during a particular period will prospectively match that beneficiary to the facility and by extension to the ESCO for the upcoming performance year. Like other accountable care organizations established by CMS, beneficiaries matched to an ESCO can seek care at any health care provider that accepts Medicare.
- **Shared savings:** The method to calculate potential shared savings or losses (for the large dialysis organizations) is similar to the Medicare Shared Savings Program. For each performance year, the ESCO's performance benchmark, which is based on the historical expenditure baseline incurred for beneficiaries who would have been aligned to the ESCO in each of the three years before the start of the first performance year for this model, will be compared with the ESCO's actual performance year average per capita expenditure amount.¹⁵ For optional performance years four and five, the performance benchmark will not be rebased using actual performance data from the first three years of the initiative. (That is, the benchmark for all five years of the initiative is based on pre-ESCO service use.)
- **Quality:** For each ESCO, CMS will calculate a total quality score using a set of standardized measures that covers five domains (patient safety, person- and caregiver-centered experience and outcome, communication and care coordination, clinical quality of care, and population health). An ESCO's performance in the ESRD QIP is reflected in the calculation of its total quality score. At the end of each performance year, shared savings or losses (if applicable) are adjusted based on the ESCO's quality performance.
- **Regulatory relief:** There are some limited waivers of the anti-kickback statute and the physician self-referral laws for ESCOs. The beneficiary inducement prohibition has been waived for certain incentives such as nonemergency transportation. The Commission previously raised concerns about the growth between 2007 and 2011 in dialysis beneficiaries' use of

nonemergency ambulance services to and from dialysis facilities and discussed the possibility of dialysis facilities providing complementary local transportation services to their beneficiaries by creating exceptions to these laws (Medicare Payment Advisory Commission 2013). In online Appendix 6-B, available at <http://www.medpac.gov>, we present updated findings that are consistent with our earlier conclusions.

The Commission has said that, if structured properly, a shared savings program—in this case, for ESRD providers—could present an opportunity to correct some of the undesirable incentives inherent in FFS payment and reward providers who are doing their part to control costs and improve quality.

In addition to the Comprehensive ESRD Care Initiative, dialysis beneficiaries in selected geographic areas also have access to ESRD special needs plans (SNPs). As of November 2015, there were about 2,700 dialysis beneficiaries enrolled in 5 SNPs operated by 3 plans in California and in Nevada. While the Comprehensive ESRD Care Initiative and ESRD SNPs enroll only dialysis beneficiaries, other accountable care organization models, such as those participating in the Medicare Shared Savings Program, might provide opportunities for beneficiaries with earlier stages of kidney disease to receive better care coordination, particularly in the management of kidney disease risk factors.

The ESRD QIP and the Dialysis Star Ratings System

CMS measures quality for each dialysis facility using two measurement systems, the ESRD QIP, which was mandated by MIPPA and implemented in 2012, and the Dialysis Star Ratings System, which CMS established through a subregulatory process in 2015. In its comment letter to CMS, the Commission questioned why CMS finds necessary a second quality system for dialysis facilities (Medicare Payment Advisory Commission 2014a). We also raised concerns that beneficiaries and their families might be confused if a facility's star and QIP scores diverge, which could occur because the measurement systems use different methods and measures to calculate a facility's performance score.

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. The two largest dialysis organizations, as well as other renal companies, appeared to have had adequate access to capital in 2015. For example, in 2015:

- DaVita entered into an agreement to acquire Renal Ventures Limited LLC, which operates 36 dialysis facilities in 6 states, and multispecialty Physician Partners and Physician Venture Partners, divisions of Renal Ventures, which operate infusion centers and vascular centers, respectively, in 3 states (DaVita 2015a). DaVita announced its acquisition of the Everett Clinic, a physician group that operates 20 care sites in the Seattle area and offers primary and specialty care and clinic care. The company expanded its international presence by forming a joint-venture kidney care specialty hospital chain in China.
- Fresenius is partnering with the Heritage Provider Network, a managed care network, to develop coordinated care networks.¹⁶ Fresenius is expanding its participation in assuming risk for the complete care of ESRD beneficiaries by seeking CMS approval to offer an MA ESRD chronic special needs plan beginning 2016 and entering into subcapitation and other shared-savings arrangements with commercial payers to provide care to MA ESRD beneficiaries (Fresenius Medical Care 2015a).¹⁷ The company expanded its international presence by acquiring a dialysis chain in Israel.
- Two midsized organizations, U.S. Renal Care Inc. and DSI Renal, finalized the merger of their companies in January 2016. Since the merger, the company operates nearly 300 facilities and serves approximately 23,000 patients in 33 states and Guam (U.S. Renal Care 2015).¹⁸ In 2013, U.S. Renal Care acquired Ambulatory Services of America (which included Innovative Dialysis Systems).
- American Renal Associates, which operates about 180 dialysis facilities through joint ventures with physicians, filed its intent with the Securities and Exchange Commission to raise up to \$100 million in an initial public offering. According to investor analysts, the initial public offering could raise \$300 million (Renaissance Capital 2015). A private equity firm (Centerbridge Partners LP), which bought a majority stake in the company in 2010, would retain a majority of the company's common stock (Armental 2015).

In public financial filings, the two largest dialysis organizations reported positive financial performance

for 2014, including strong organic volume and revenue growth—that is, growth achieved apart from mergers and acquisitions.

Factors unrelated to Medicare’s payment policies could affect providers’ access to capital. In 2015, DaVita reached a final agreement to pay \$450 million to settle a whistle-blower lawsuit (without admitting liability) claiming that the company intentionally inflated Medicare billings for medication waste (DaVita 2015b).¹⁹ Despite this settlement, in 2015 assessments, investor analysts concluded that DaVita’s core dialysis segment continues to perform very well, and they anticipate solid growth in the dialysis sector.

In general, current trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is attractive to for-profit providers.

Medicare payments and providers’ costs

Each year, we examine the relationship between Medicare’s payments and providers’ costs as part of our assessment of payment adequacy. To make this assessment, we reviewed Medicare expenditures for outpatient dialysis services in 2014 and examined trends in spending under the PPS. We also reviewed evidence regarding providers’ costs under the PPS.

Medicare payments for outpatient dialysis services

Between 2013 and 2014, total Medicare spending increased by about 1 percent, from \$11.0 billion to \$11.2 billion, while per capita spending decreased by 0.5 percent, from about \$29,300 to about \$29,200 (annual percent change in spending is based on data that is not rounded). The small decline in per capita spending primarily reflects the rebasing of the base payment rate in 2014 (from \$240.36 per treatment to \$239.02 per treatment in 2013 and 2014, respectively) to reflect the decreased use of dialysis drugs. The change during this period in total and per capita spending also reflects the 2 percent sequester reduction on Medicare’s payment to providers that began in April 2013.

Part D spending for dialysis drugs

Between 2011 and 2013, the use of dialysis drugs included in the PPS payment bundle declined. By contrast, during this period, the use (as measured by Medicare spending) of Part D dialysis drugs that are not yet included in the PPS payment bundle increased. In 2013 (the most recent year data are available), Part D spending for two

categories of dialysis drugs (calcimimetics and phosphate binders) totaled \$1.3 billion, an increase of 22 percent per year compared with 2011. During this period, on a per treatment basis, Part D spending for dialysis drugs increased by 19 percent per year.²⁰ In addition, between 2011 and 2013, total Part D spending for dialysis drugs grew more rapidly than total Part D spending for dialysis beneficiaries (22 percent vs. 13 percent, respectively). In 2013, Part D spending for dialysis drugs constituted 53 percent of dialysis beneficiaries’ gross Part D spending. Medicare spending for Part D dialysis drugs is not included in the Commission’s analysis of Medicare’s payments and costs for dialysis facilities.

The Secretary intended that the dialysis PPS payment bundle, beginning in 2014, include Part D dialysis drugs. Most recently, the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 delayed bundling these drugs until 2025. However, if an injectable equivalent (or other form of administration rather than an oral form) of the oral-only drug is approved by the Food and Drug Administration before 2025, CMS will include both the oral and non-oral versions in the PPS payment bundle (Centers for Medicare & Medicaid Services 2015). Including dialysis drugs covered under Part D in the Part B payment bundle may lead to better management of drug therapy and improve beneficiaries’ access to these medications since some beneficiaries lack Part D coverage or have coverage less generous than the Part D standard benefit. Potential incentives to use a Part D drug instead of a drug covered under the bundle, a situation that might not result in the best care, would be eliminated. The decision-making process would be based on what is best for the patient.

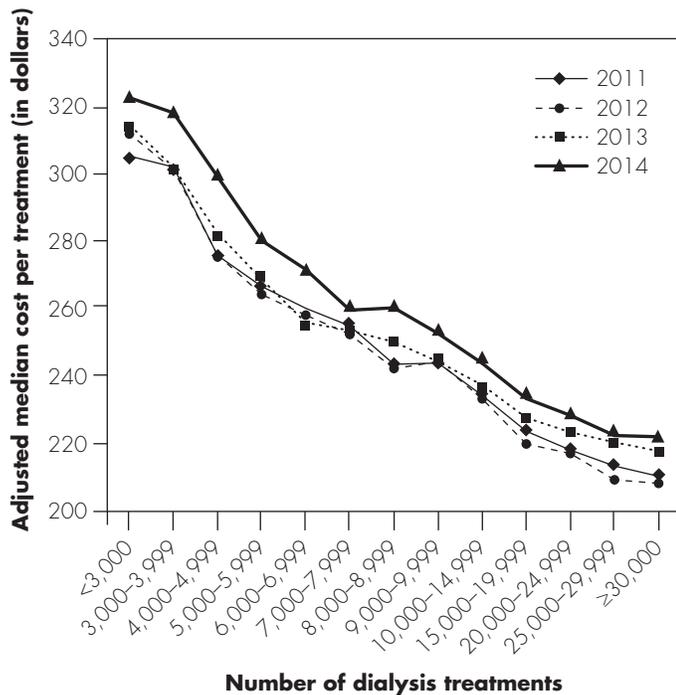
Providers’ costs for outpatient dialysis services under the new PPS

To assess the appropriateness of costs for dialysis services paid for under the new PPS, we examine whether aggregate dialysis facility costs reflect costs that efficient providers would incur in furnishing high-quality care. For this analysis, we use 2013 and 2014 cost reports submitted to CMS by freestanding dialysis facilities. For those years, we look at the growth in the cost per treatment and how total treatment volume affects that cost.

Cost growth under the PPS Between 2013 and 2014, the cost per treatment rose by about 1 percent, from about \$240 per treatment to \$243 per treatment. 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 2013

FIGURE 6-5

Higher volume dialysis facilities have lower cost per treatment, 2011-2014



Note: Cost per treatment is adjusted to remove differences in the cost of labor. Dialysis treatments include those paid for by all sources (not just Medicare-paid treatments).

Source: MedPAC analysis of 2011-2014 cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

and 2014, per treatment costs decreased by 4 percent for facilities in the 25th percentile of cost growth and increased by 5 percent for facilities in the 75th percentile.

Cost per treatment is correlated with facility service volume Cost per treatment is correlated with the total number of treatments a facility provides. For this analysis, we adjusted the cost per treatment to remove differences in the cost of labor across areas and included all treatments regardless of payer. Our analysis showed, in each year from 2011 through 2014, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-5). That is, the greater the facility’s service volume, the lower its costs per treatment.

Medicare margin for freestanding facilities in 2014

The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by

comparing Medicare’s payments with facilities’ Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2014.

For 2014, we estimate that the aggregate Medicare margin was 2.1 percent (Table 6-5). Margins decidedly vary by treatment volume. In 2014, facilities in the lowest volume quintile had margins at or below -15.4 percent, and facilities in the top volume quintile had margins of 8.1 percent or greater.

Urban facilities had higher margins than rural facilities (2.9 percent and -2.7 percent, respectively). Much of the difference in margin between urban and rural facilities is accounted for by differences in total treatment volume. Urban dialysis facilities are larger on average than rural facilities with respect to number of treatment stations and Medicare treatments provided. In 2014, urban facilities averaged 12,323 treatments while rural facilities averaged 7,720 treatments.

Another piece of information to consider in evaluating the adequacy of payments is to assess whether providers have a financial incentive to expand the number of Medicare beneficiaries they serve. In considering whether to treat an additional patient, the provider compares the marginal revenue it will receive (i.e., the Medicare payment) with its marginal costs—that is, the costs that vary with volume. If Medicare payments are larger than the marginal costs of treating an additional beneficiary, a provider has a financial incentive to increase its volume of Medicare beneficiaries. On the other hand, if marginal payments do not cover the marginal costs, the provider may have a disincentive to admit Medicare beneficiaries. To operationalize this concept, we compare payments for Medicare services with marginal costs, which is approximated as:

$$\text{Marginal profit} = (\text{payments for Medicare services} - (\text{total Medicare costs} - \text{fixed building and equipment costs})) / \text{Medicare payments}$$

This formula gives a lower bound on the marginal profit because we ignore any potential labor costs that are fixed. For dialysis facilities, we find that excluding capital costs lowers the cost per treatment by nearly \$40, and that Medicare payments exceed marginal costs by nearly 18 percent, suggesting facilities with available capacity have

**TABLE
6-5**

Medicare margin in 2014 varied by type of freestanding dialysis facility

Provider type	Medicare margin	Medicare marginal profit	Percent of freestanding dialysis facilities
All	2.1%	17.9%	100%
Urban	2.9	18.4	80
Rural	-2.7	15.1	20
Treatment volume (quintile)			
Lowest	-15.4	10.2	20
Second	-6.6	13.3	20
Third	-0.6	16.6	20
Fourth	3.8	18.9	20
Highest	8.1	20.7	20

Source: Compiled by MedPAC from 2014 cost report and outpatient claims submitted by facilities to CMS and the 2014 Dialysis Compare database.

an incentive to treat Medicare beneficiaries. This incentive is a positive indicator of patient access.

Projecting the Medicare margin for 2016

On the basis of 2014 payment and cost data, provider cost growth between 2013 and 2014, and policy changes that have gone into effect between 2014 (the year of our most recent margin estimates) and 2017, we project a 0.8 percent aggregate Medicare margin for dialysis facilities in 2016. The policy changes that are included in this projection include:

- statutory updates of 0 percent in 2015 and 0.2 percent in 2016;
- other regulatory changes that resulted in increased payments in 2015 of 0.3 percent;
- a reduction in payments due to the ESRD QIP in 2015 and 2016 of 0.17 percent in each year; and
- the sequester, which is now fully reflected in Medicare’s payments to providers.

How should Medicare payments change in 2017?

The Protecting Access to Medicare Act of 2014 sets the update to the outpatient dialysis payment base rate equal to the ESRD market basket index, less an adjustment

for productivity (currently estimated at 0.5 percent) and 1.25 percentage points. Based on CMS’s latest forecast of changes in the ESRD market basket costs for calendar year 2017 (2.3 percent), the update to the 2017 payment rate would be 0.55 percent. In addition to this statutory provision, the ESRD QIP is expected to decrease total payments by 0.13 percent in 2017.

Update recommendation

The evidence on payment adequacy suggests that outpatient dialysis payments are adequate. It appears that facilities have become more efficient under the PPS, as measured by declining use of most injectable dialysis drugs between 2010 and 2014.

RECOMMENDATION 6

The Congress should increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2017.

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. Providers have become more efficient in the use of dialysis drugs under the PPS. The Medicare margin was 2.1 percent in 2014 and is projected to be 0.8 percent in 2017.

Spending

- In 2017, the statute sets the payment update at the market basket, net of the productivity adjustment, minus 1.25 percentage points. The Commission’s recommendation would have no effect on federal program spending relative to the statutory update.

Beneficiary and provider

- This recommendation is expected to have a minimal effect on reasonably efficient providers’ willingness and ability to care for Medicare beneficiaries. We do not anticipate any negative effects on beneficiary access to care.

Regulatory improvements to the dialysis PPS

To address two concerns with the dialysis PPS, we are reiterating our prior recommendation that the Congress direct the Secretary to (1) focus the low-volume payment adjustment on protecting facilities critical to beneficiary access, and (2) examine the accuracy of dialysis cost report data under the PPS (see text box for recommendation language). The Secretary has the authority to make these regulatory changes.

The low-volume payment adjustment should focus on protecting only facilities critical to beneficiary access

The low-volume payment adjustment implemented in 2011 and in 2016 does not target facilities that might be critical to beneficiary access (Medicare Payment Advisory Commission 2014c). The distance requirement does not prevent facilities that are close to other facilities from receiving the payment adjustment to their base rate. Medicare and dialysis beneficiaries would be better served by an adjuster that targets low-volume facilities that are not close to another facility. Only low-volume facilities that are necessary to maintain access—those located in isolated areas—should receive enhanced payment.

Issues and analysis

For both of the low-volume adjustment factors implemented in 2011 and 2016, CMS defines a low-volume facility as one that provided fewer than 4,000 treatments (Medicare and non-Medicare) in each of the three years before the payment year and that has not opened, closed, or received a new provider number

because of a change in ownership. The refined low-volume payment adjustment (implemented in 2016) differs from the prior definition by:

- including, for the purposes of determining eligibility, treatments furnished by the facility in question and other facilities in common ownership that are within five road miles from the facility in question. Before 2016, a 25-mile criterion was applied.
- applying the five-mile distance criterion to all facilities (regardless of when the facility was certified). Before 2016, the 25-mile criterion applied only to facilities certified on or after January 1, 2011.

In addition to the low-treatment-volume adjuster, CMS in 2016 added a new payment adjuster for all facilities located in rural areas, regardless of a facility’s geographic proximity to the closest facility and treatment volume. A rural area would be defined as any area outside of an urban area. The low-volume and rural adjustments are separate, meaning that a facility meeting both criteria could receive both payment adjustments.

The Commission is concerned that neither the low-volume adjustment nor the rural adjustment are targeting facilities that are critical to beneficiary access:

- The low-volume adjustment implemented in 2016 imposes only a distance requirement for facilities under common ownership. According to our analysis, about 47 percent of the facilities that would receive this adjustment are within five miles of the next closest facility. The median distance between the facility that would receive the adjustment and the next closest facility is six miles.
- The rural adjustment does not impose a distance requirement between a facility that would receive this adjustment and the next closest facility. About 28 percent of all rural facilities are within five miles of the next closest facility. We are also concerned that the rural adjustment does not consider facilities’ total treatment volume. Nearly 20 percent of facilities located in rural areas are high volume, and total volume is correlated with cost per treatment.²¹ Thus, the fact that the facilities are designated rural does not in and of itself indicate that these facilities warrant special payment adjustments to ensure access to care. These findings suggest that there is great diversity among areas designated as rural.

The Commission reiterates its March 2014 recommendation for redesigning the low-volume payment adjustment and auditing dialysis facilities' cost reports

Recommendation 6–2, March 2014 report

The Congress should direct the Secretary to:

- redesign the low-volume payment adjustment to consider a facility's distance to the nearest facility and
- audit dialysis facilities' cost report data.

Rationale 6–2, March 2014 report

This recommendation would target the low-volume payment adjustment only at facilities that are isolated and would help ensure that dialysis facilities' cost reports are accurate.

Implications 6–2, March 2014 report

Spending

- This recommendation would redistribute payments to low-volume facilities. When this recommendation was made in March 2014, the spending implications were that it would be budget neutral relative to current law.

The Protecting Access to Medicare Act of 2014 required that the Secretary of Health and Human Services conduct audits of Medicare cost reports beginning in 2012 for a representative sample of providers of services and renal dialysis facilities furnishing renal dialysis services. To support this effort, the law authorized the Secretary to transfer \$18 million (in fiscal year 2014) from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. As of January 2016, CMS has not announced results from this audit.

Beneficiary and provider

- This recommendation should help ensure that beneficiaries' access to care is maintained at isolated, low-volume facilities under the prospective payment system. The recommendation is not expected to affect providers' willingness or ability to serve beneficiaries. Payments would decrease for facilities who currently receive the low-volume payment adjustment but are in close proximity to other facilities and would increase for facilities that have lower treatment volumes and are not in close proximity to other facilities, but that currently do not receive the low-volume payment adjustment. ■

CMS should design a single payment adjustment that targets low-volume isolated facilities instead of two separate adjustments for low volume and rural location. Dialysis beneficiaries and Medicare would be better served by a single adjuster that targets low-volume facilities that are not close to another facility.

As suggested by the Government Accountability Office, CMS should consider designing an adjustment that does not give facilities an incentive to limit services to avoid reaching the low-volume treatment threshold (the so-called cliff effect) (Government Accountability Office 2013). A payment approach that decreases the payment adjustment as facility volume increases might reduce this incentive.

Dialysis facilities' cost report data under the PPS should be examined for accuracy

In the Commission's 2014 report to the Congress, we raised concerns that CMS had not yet examined the

appropriateness of the costs that facilities include in their cost reports under the PPS (Medicare Payment Advisory Commission 2014c). In our comment letters to CMS, we raised concerns that CMS used unaudited cost reports to recalibrate the dialysis market basket (in 2015) and refine the payment adjustment factors (in 2016).

Based on our 2014 recommendation, the Protecting Access to Medicare Act of 2014 funded CMS to audit a representative sample of ESRD facility cost reports beginning in 2012.

Issues and analysis

It is important to examine the accuracy of facilities' cost reports for several reasons. First, it is basic fiscal management to ensure that facilities' cost reports are accurate. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's

payments for dialysis services. If providers overstate costs, analysis will understate the Medicare margin. Medicare cost principles are designed to ensure that Medicare pays reasonable expenses related to patient care. Second, it has been more than 10 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change. The Commission's analysis of 2014 freestanding facilities' cost reports shows significant variation across facilities in the level and the distribution of cost per treatment.

Third, historically, unaudited cost reports have included costs that Medicare does not allow. Analysis of previous audits (in 1988, 1991, 1996, and 2001) of dialysis facilities' cost reports found that facilities' allowable costs ranged from 90 percent to 96 percent of costs submitted. CMS's recent audit of a sample of 100 home health agency cost reports demonstrates the importance of validating these data. The agency found that agencies

in the audit sample overstated their costs by an average of about 8 percent (Centers for Medicare & Medicaid Services 2013).

Medicare's contractors (e.g., Medicare administrative contractors) and the Department of Health and Human Services' Office of Inspector General have conducted past audits of dialysis facilities' cost reports (Government Accountability Office 1993). Medicare administrative contractors conducted the recent audit of cost reports submitted by home health agencies. To ensure that audits are thorough and complete, auditors should (1) evaluate whether the reported costs are supported by facilities' accounting records, (2) assess whether the costs are reasonable and related to patient care, and (3) assess the appropriateness of transactions with affiliated entities—called related organizations—that are under common ownership or control. ■

Endnotes

- 1 The term *dialysis drugs* refers to the medications used to treat ESRD.
- 2 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to individuals who may or may not be covered by Medicare.
- 3 Age groups are 19 years or younger, 20 to 44 years, 45 to 64 years, 65 to 74 years, and 75 years or older.
- 4 For individuals entitled to Medicare based on ESRD, 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 dialyzing at home.
- 5 Medicare pays dialysis facilities for uncollected deductibles and coinsurance (bad debt). In fiscal year 2015 and beyond, Medicare paid 65 percent of allowable bad debt.
- 6 These drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the dialysis PPS.
- 7 Price growth across all dialysis drugs is calculated by multiplying the change in each drug's price per unit by the drug's share of total 2014 volume.
- 8 Anemia is measured by a blood test to check the level of hemoglobin, the protein that carries oxygen in red blood cells.
- 9 Blood transfusions are of concern to patients because they (1) carry a small risk of transmitting blood-borne infections to the patient, (2) may cause some patients to develop a reaction, and (3) are costly and inconvenient to patients. Blood transfusions are of particular concern for patients seeking kidney transplantation because they increase a patient's alloantigen sensitization, which can require a patient to wait longer to receive a transplant.
- 10 PD is the dominant home method; about 85 percent of patients dialyzing at home receive PD (United States Renal Data System 2015).
- 11 Press accounts also report that the manufacturer has limited the size of shipments sent to existing PD patients (Pfeifer and Terhune 2014).
- 12 To alleviate the shortage, Baxter (1) received Food and Drug Administration approval to import PD solutions from Ireland, (2) bought PD solutions from Fresenius to distribute to its customers (Seaborg 2015), and (3) announced additional manufacturing capacity in 2015 (Baxter 2014). In addition, Fresenius announced its PD manufacturing facility would be operational in early 2017 and announced in November 2015 its partnership with a Swiss manufacturer to develop a portfolio of peritoneal technologies (Fresenius Medical Care 2015b, Zumoff 2015).
- 13 This analysis used 100 percent of 2011 through 2014 carrier and outpatient claims submitted for KDE services.
- 14 MIPPA does not permit other providers (including registered nurses, social workers, and dieticians) and dialysis facilities to bill for KDE services. In 2014, KDE services were most frequently provided by nephrologists, nurse practitioners, or physician assistants in an office setting.
- 15 In each year of the initiative, the ESCO's performance benchmark is calculated by adjusting the historical expenditure baseline for changes in medical spending and risk adjusted for changes in case mix. In addition, for the large ESCOs, a discount will be applied to the nondialysis component of their performance-year benchmark: 1 percent in year 2, 2 percent in year 3, and 3 percent in years 4 and beyond.
- 16 Heritage will acquire or build coordinated care networks, and Fresenius will furnish renal, vascular, and related services for covered members.
- 17 Under these arrangements, Fresenius and the payer establish a baseline per patient per month amount, and Fresenius retains the difference if the company provides care for less than the baseline. If the cost of complete care exceeds the baseline, Fresenius owes the payer the difference (Fresenius Medical Care 2015a).
- 18 In 2015, U.S. Renal Care operated 198 facilities in 20 states and Guam, and DSI operated 100 facilities in 22 states (U.S. Renal Care 2015).
- 19 The lawsuit, filed in 2007, said DaVita violated the False Claims Act by using dosing guidelines designed to maximize the medication waste (intentionally inflating its claims for discarded medications) for a vitamin D drug (Zemplar), and an iron agent (Venofer).

20 Part D spending per dialysis treatment is calculated by dividing total Part D spending for dialysis drugs by the total number of Part B dialysis treatments furnished by dialysis facilities to Medicare beneficiaries with and without Part D.

21 Using 2013 cost reports submitted by freestanding ESRD facilities and CMS's impact file, high-volume facilities located in rural areas had lower total adjusted cost per treatment for PPS payment bundle services than low-volume facilities located in rural areas (median cost of \$239 per treatment and \$312 per treatment, respectively).

References

- Armental, M. 2015. American Renal Associates files for IPO. *Wall Street Journal*, August 31.
- Baxter. 2014. Letter from Richard Marritt, Region Head and General Manager, US and Canada. July 28. [http://www.homebybaxter.com/Documents/USMP%20MG2%2014-0093i_Customer%20Letter%20\(Update\)_FINAL.pdf](http://www.homebybaxter.com/Documents/USMP%20MG2%2014-0093i_Customer%20Letter%20(Update)_FINAL.pdf).
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Medicare program; end-stage renal disease prospective payment system, and quality incentive program. Final rule. *Federal Register* 80, no. 215 (November 16): 68967–69077.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2014. *End-stage renal disease prospective payment system: Overview of 2011–2014 claims-based monitoring program*. Baltimore, MD: CMS.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013. Medicare and Medicaid programs; home health prospective payment system rate update for CY 2014, home health quality reporting requirements, and cost allocation of home health survey expenses. Final rule. *Federal Register* 78, no. 231 (December 2): 72256–72320.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. *Medicare provider reimbursement manual – Part 1*. Chapter 21. Baltimore, MD: CMS.
- DaVita. 2015a. DaVita HealthCare Partners to acquire Renal Ventures. Press release. August 24. <http://pressreleases.davitahealthcarepartners.com/2015-08-24-DaVita-HealthCare-Partners-to-Acquire-Renal-Ventures>.
- DaVita. 2015b. Quarterly report (Form 10–Q). Filing submitted to the Securities and Exchange Commission, March 31. <http://phx.corporate-ir.net/phoenix.zhtml?c=76556&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbnmcu eG1sP2lwYWdlPTEwMjQ5NjQzJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVEIPTl9FTIRJUKUmc3Vic2lkPTU3>.
- Ephraim, P. L., N. R. Powe, H. Rabb, et al. 2012. The providing resources to enhance African American patients’ readiness to make decisions about kidney disease (PREPARED) study: protocol of a randomized controlled trial. *BMC Nephrology* 13: 135.
- Fresenius Medical Care. 2015a. *Form 6–K*. Report of foreign private issuer. http://www.freseniusmedicalcare.com/fileadmin/data/de/pdf/investors/News___Publications/Financial_Report/2015/Q2_2015_6-K.pdf.
- Fresenius Medical Care. 2015b. Fresenius Medical Care’s Knoxville manufacturing plant on schedule to help ease nationwide shortage of peritoneal dialysis solution. Press release. November 5. <http://newsroom.fmcna.com/wordpress/2015/11/05/fresenius-medical-cares-knoxville-manufacturing-plant-on-schedule-to-help-ease-nationwide-shortage-of-peritoneal-dialysis-solution/>.
- Government Accountability Office. 2015. *End-stage renal disease: Medicare payment refinements could promote increased use of home dialysis*. Washington, DC: GAO.
- Government Accountability Office. 2013. *End-stage renal disease: CMS should improve design and strengthen monitoring of low-volume adjustment*. Report 13–287. Washington, DC: GAO.
- Government Accountability Office. 1993. *Medicare: Renal facility cost reports probably overstate costs of patient care*. Report 93–70. Washington, DC: GAO.
- Medicare Payment Advisory Commission. 2014a. Comment letter to CMS on the end-stage renal disease prospective payment system and quality incentive program proposed rule, August 15.
- Medicare Payment Advisory Commission. 2014b. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2014c. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2001. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Medicare Payment Advisory Commission. 2000. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- Neumann, M. 2014. Baxter, FMC sign supply agreement; ISPD ‘deeply concerned’ about PD fluid shortage. *Nephrology News & Issues*, September 3.
- Pfeifer, S., and C. Terhune. 2014. Shortage of in-home dialysis solution has patients worried. *LA Times*, September 12.

Renaissance Capital. 2015. Debt and dialysis: LBO American Renal Associates files for an IPO that could raise \$300 million. <http://www.nasdaq.com/article/debt-and-dialysis-lbo-american-renal-associates-files-for-an-ipo-that-could-raise-300-million-cm515322>.

Rettig, R. A., and N. G. Levinsky. 1991. *Kidney failure and the federal government*. Washington, DC: National Academy of Sciences.

Seaborg, E. 2015. Peritoneal dialysis fluid shortage disrupted growth of popular therapy. *Kidney News*, March.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2015. *USRDS 2015 annual data report*. Bethesda, MD: NIDDK.

U.S. Renal Care. 2015. U.S. Renal Care and DSI Renal announce definitive merger agreement. Press release. August 22. <http://www.usrenalcare.com/article/us-renal-care-and-dsi-renal-announce-definitive-merger-agreement>.

Zumoff, R. 2015. Fresenius partners with Swiss device maker to build new peritoneal dialysis machines. *Nephrology News & Issues*, November 3.