

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 2018.

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

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2015, nearly 388,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from nearly 6,500 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. The bundle includes certain dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2015, Medicare expenditures for outpatient dialysis services were \$11.2 billion, a slight decline of 0.1 percent compared with 2014 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. Between 2014 and 2015, growth in the number

In this chapter

- Are Medicare payments adequate in 2017?
- How should Medicare payments change in 2018?

of dialysis treatment stations grew slightly faster than the growth in the number of dialysis beneficiaries.

- **Volume of services**—Between 2014 and 2015, the number of FFS dialysis beneficiaries grew by 1.1 percent, while the total number of treatments grew by 0.4 percent. At the same time, the per treatment use of most dialysis injectable drugs (including erythropoiesis-stimulating agents (ESAs), which are 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—We looked at changes in quality indicators between 2011, when the outpatient dialysis PPS was implemented, and 2015. There was a declining trend in unadjusted mortality, hospitalization, and 30-day readmission rates, though emergency department use increased. With regard to anemia management, negative cardiovascular outcomes associated with high ESA use declined, and blood transfusion use, which initially increased under the PPS, trended down in 2014 and 2015. Beneficiaries' use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 9 percent to 11 percent of dialysis beneficiaries. However, home dialysis growth slowed between 2014 and 2015 because of a shortage of the dialysis solutions needed for the predominant home method, peritoneal dialysis. Another important aspect of quality is the appropriate timing of the initiation of dialysis. A potential concern is that the proportion of patients with higher levels of residual kidney function upon the initiation of dialysis increased from 13 percent in 1996 to 43 percent in 2010.

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. Since 2010, the two largest dialysis organizations have grown through acquisitions and mergers with midsized dialysis organizations and other providers, including physician services organizations.

Medicare payments and providers' costs—Our analysis of Medicare payments and costs is based on 2014 and 2015 claims and cost report data submitted to CMS by freestanding dialysis facilities. During this period, cost per treatment increased by 0.5 percent, while Medicare payment per treatment decreased by about 1.3 percent. Taking into account the sequester, we estimate that the aggregate Medicare margin was 0.4 percent in 2015, and the rate of marginal profit—that is, the rate at which Medicare payments exceed providers' marginal cost—was 16.6 percent. We project a 2017 Medicare margin of –1.0 percent, which reflects a CMS accounting change

that raises average costs. Without that change, the projected 2017 margin would be about the same as our estimate of the margin for 2015. The Commission therefore recommends that the Congress increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2018. ■

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. 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.

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 cleansing fluid (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 2015, about 388,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from nearly 6,500 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 2015, 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—a calcimimetic and multiple phosphate binders—that are not yet included in the PPS payment bundle totaled \$1.5 billion in 2014 (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 ESRD, including those under age 65. To qualify for the ESRD program, an individual must be fully or currently

**TABLE
6-1**

FFS dialysis beneficiaries are disproportionately younger, male, and African American compared with all Medicare FFS beneficiaries, 2015

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
Age		
Under 45 years	11%	4%
45–64 years	38	13
65–74 years	27	48
75–84 years	18	23
85+ years	6	12
Sex		
Male	55	47
Female	45	53
Race		
White	48	81
African American	36	10
All others	17	9
Residence, by type of county		
Urban	82	78
Rural micropolitan	11	13
Rural, adjacent to urban	5	6
Rural, not adjacent to urban	3	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 2015 enrollment data and claims submitted by dialysis facilities to CMS.

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.

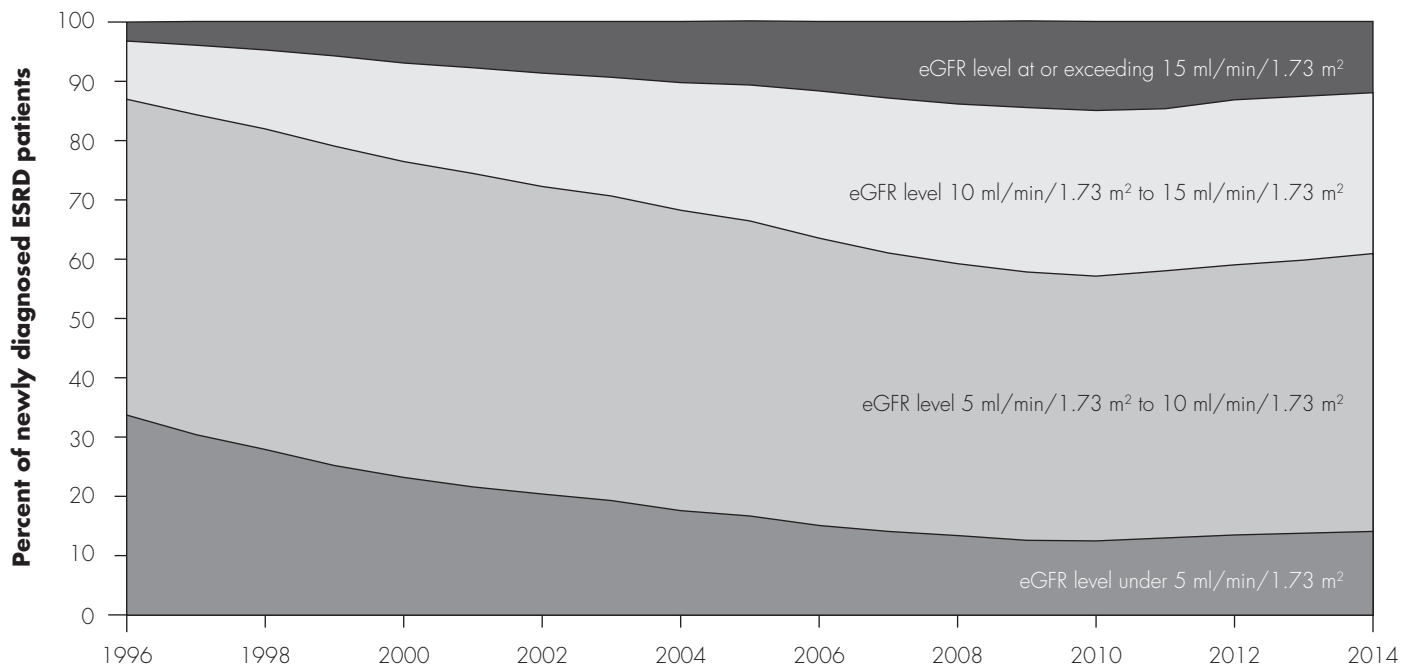
Most dialysis beneficiaries have FFS coverage. The statute prohibits enrollment of individuals with ESRD in Medicare Advantage (MA) plans. However, beneficiaries who were enrolled in a managed care plan before an

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 2015, about 17 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).³

In 2015, a majority (90 percent) of FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage. In 2015, 70 percent of FFS dialysis beneficiaries with Part D coverage received the low-income subsidy, and 10 percent of FFS dialysis beneficiaries in 2015 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 2015, 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, 47 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). FFS dialysis beneficiaries were more likely to be dually eligible for Medicaid and Medicare, compared with all Medicare FFS beneficiaries (48 percent vs. 18 percent, respectively; data not shown).

Between 2004 and 2014 (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 353 per million people (United States Renal Data System 2016). Since peaking in 2006, the adjusted rate declined or remained the same across all races and ethnicities (White, African American, Asian Americans, Native American, and Hispanic) and all age groups (United States Renal Data System 2016).⁴ In 2015, 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).⁵

FIGURE 6-1**Dialysis has been initiated with higher levels of residual kidney function since 1996**

Note: eGFR (estimated glomerular filtration rate). “Higher levels of residual kidney function” refers to patients with an eGFR (a measure of residual kidney function) above 10 milliliters per minute per 1.73 square meters. (Lower values of this measure suggest reduced residual kidney function.) Population includes only newly diagnosed patients with CMS Form 2728. eGFR is calculated using the chronic kidney disease epidemiology calculation (CKD-EPI) equation (CKD-EPI eGFR (ml/min/1.73 m²) for patients 18 years and older and the Schwartz equation for patients under the age of 18 years.

Source: United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2016. *USRDS 2016 annual data report*. Bethesda, MD: NIDDK.

Data from the mid-1990s through 2014 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease (CKD) (United States Renal Data System 2016). The proportion of patients with higher levels of residual kidney function steadily increased between 1996 and 2010, from 13 percent to 43 percent (Figure 6-1). Higher levels of residual kidney function refer to patients with an estimated glomerular filtration (eGFR) rate (a measure of residual kidney function) above 10 milliliters per minute per 1.73 square meters (lower values of this measure suggest comparatively less residual kidney function). While the share of patients initiating dialysis earlier in the course of CKD has decreased modestly since 2011, the share remains three times higher than in 1996. Researchers have questioned this early initiation of dialysis in those with late-stage CKD, concluding that it was not associated with improved survival or clinical outcomes (Cooper et al. 2010, Evans et al. 2011, Kazmi et al. 2005, Stel et al. 2009, Traynor et al. 2002). For

example, Cooper and researchers found that survival is similar between patients for whom dialysis is initiated early (with an eGFR equal to 10.0 to 14.0 ml per minute) and those for whom dialysis is electively delayed (with an eGFR equal to 5.0 to 7.0 ml per minute) and concluded that dialysis can be delayed for some patients until the eGFR drops below 7.0 ml per minute or until more traditional clinical indicators for the initiation of dialysis are present (Cooper et al. 2010). The Commission intends to continue to monitor this trend.

Better primary care management of the risk factors for CKD—particularly hypertension and diabetes, which together are the primary cause of roughly 7 of 10 new ESRD cases—can help prevent or delay the illness’s onset (United States Renal Data System 2016). 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

**TABLE
6-2**

Current payment adjustment factors for the dialysis PPS

Payment adjuster	Value of payment adjuster
Age	
18–44 years	1.257
45–59 years	1.068
60–69 years	1.070
70–79 years	1.000
80+ years	1.109
Body surface area (per 0.1 m ²)	1.032
Underweight (body mass index < 18.5 kg/m ²)	1.017
Time since onset of dialysis (<4 months)	1.327
Comorbidities	
Pericarditis	1.040
Gastrointestinal tract bleeding	1.082
Hereditary hemolytic/sickle cell anemia	1.192
Myelodysplastic syndrome	1.095
Facility low-volume status	1.239
Facility rural status	1.008

Note: PPS (prospective payment system). Payment adjustment factors are for ages 18 and older. The base payment rate is also adjusted for local input prices on a facility-level basis.

Source: 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.

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) the facilities that provide dialysis treatments in a dialysis center or that 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 our work in this report 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 that began in 2015, involving facilities and nephrologists.

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 billable separately. 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

Significant changes to the outpatient dialysis PPS

Since its implementation in 2011, the dialysis prospective payment system (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 (available at http://medpac.gov/docs/default-source/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. More information about these payment changes can be found in the Commission's March 2016 report to the Congress (available at <http://medpac.gov/docs/default-source/reports/chapter-6-outpatient-dialysis-services-march-2016-report-.pdf?sfvrsn=0>). ■

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. Table 6-2 provides the payment adjusters for the PPS: patient-level characteristics (age, body measurement characteristics, onset of dialysis, and selected acute and chronic comorbidities) and facility-level factors (low treatment volume, rural location, and local input prices) applied to the base payment rate in 2016. Medicare pays facilities furnishing dialysis treatments in the 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 2016, the ESRD Quality Incentive Program held facilities responsible for the quality of care they provide, using eight clinical measures and three 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/docs/default-source/payment-basics/medpac_payment_basics_16_dialysis_final.pdf?sfvrsn=0).

Since it was implemented in 2011, the outpatient dialysis PPS has undergone two significant changes—rebased of the base payment rate in 2014 and recalibrating and redefining the payment adjusters in 2016. The text box on this page summarizes these changes.

Are Medicare payments adequate in 2017?

To address whether payments for 2017 are adequate to cover the costs that efficient providers incur and how much providers' costs should change in the update year (2018), 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.
- Some quality measures show improvement, while others need improvement.
- Provider access to capital is sufficient.
- The 2015 Medicare outpatient dialysis margin is estimated at 0.4 percent, and the rate of marginal profit is 16.6 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.

**TABLE
6-3**

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

	2015				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	
					2010-2014	2014-2015	2010-2014	2014-2015
All	45.1	6,475	113,400	18	3%	3%	3%	2%
	Percent of total							
Freestanding	94%	93%	95%	18	4	3	4	3
Hospital based	6	7	5	14	-6	-3	-6	-3
Urban	84	80	83	18	4	3	3	3
Rural, micropolitan	11	13	11	16	1	2	2	2
Rural, adjacent to urban	3	5	4	13	2	1	2	1
Rural, not adjacent to urban	2	3	2	12	2	3	2	4
Frontier	0.2	0.6	0.3	11	1	0	5	1
For profit	90	87	88	18	4	3	4	3
Nonprofit	10	13	12	17	-3	0	-2	0
Two largest dialysis organizations	75	71	73	18	7	3	6	3
All others	25	29	27	17	-3	2	-3	2

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 2010, 2014, and 2015 Dialysis Compare database from CMS and 2015 claims submitted by freestanding and hospital-based dialysis facilities to CMS.

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 2010 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). By contrast, between 2010 and 2014, the number of beneficiaries grew 2 percent annually (data not shown). In the same period, 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 (-6 percent

and -2 percent, respectively). Between 2010 and 2014, capacity at urban facilities grew at 3 percent per year while capacity at all rural facilities (data not shown) grew at 2 percent per year. Total dialysis capacity between 2014 and 2015 grew at rates similar to rates in 2010 to 2014.

Providers of outpatient dialysis services

In 2015, there were roughly 6,500 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 2015, freestanding facilities furnished 94 percent of FFS treatments, and for-profit facilities furnished about 90 percent (Table 6-3). In 2015, the capacity of facilities located in urban and rural

**TABLE
6-4**

Annual growth in the number of FFS beneficiaries and treatments, 2009–2015

	2009	2010	2011	2012	2013	2014	2015
Percent annual growth in the number of beneficiaries	4%	4%	2%	2%	2%	2%	1%
Percent annual growth in the number of total treatments	4	5	3	3	2	2	0.4
Number of non-annualized treatments per beneficiary	113	114	115	117	117	117	116

Note: FFS (fee-for-service). The growth rates reported reflect the percent change between that year and the prior year.

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

areas was generally consistent with where FFS dialysis beneficiaries lived.

Two large dialysis organizations (LDOs) dominate the dialysis industry. In 2015, these two LDOs accounted for about 70 percent of all facilities and 75 percent of all Medicare treatments. In addition to operating most dialysis facilities, these 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 Phase I–IV 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.

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 Service file, we compared the characteristics of beneficiaries treated by facilities that closed in 2014 with the beneficiaries of facilities that provided dialysis in 2014 and 2015, the most current years for which complete data are available.

Between 2014 and 2015, the number of dialysis treatment stations—a measure of providers’ capacity—increased by 2 percent. There was a net increase in the number of facilities that are freestanding, for profit, and located in both urban and rural areas. Compared with facilities that treated beneficiaries in both years, facilities that closed in 2014 (about 60 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 (Table 6-3).

According to our analysis, few dialysis beneficiaries (about 2,100 individuals) were affected by facility closures in 2014. 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 2014 and 2015, the average annual growth of total dialysis treatments (0.4 percent) was slower than the average annual growth of beneficiaries (1 percent) (Table 6-4). While the non-annualized number of dialysis treatments per beneficiary dropped between 2014 and 2015 from about 117 treatments to 116 treatments, the number remains higher than levels seen between 2009 and

**TABLE
6-5**

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

Dialysis drug	Mean units per treatment*			Aggregate percent change		
	2007	2010	2015	2007-2010	2010-2014	2014-2015
ESAs						
Epoetin alfa	5,532	5,214	2,197	-6%	-45%	-23%
Darbepoetin alfa	1.52	1.26	1.36	-17	-40	81
Epoetin beta**	N/A	N/A	1.35	N/A	N/A	N/A
Iron agents						
Sodium ferric gluconate	0.39	0.15	0.12	-62	-17	-5
Iron sucrose	12.3	16.0	12.8	30	-19	-1
Ferumoxytol	N/A	0.8	0.01	N/A	-98	-49
Vitamin D agents						
Paricalcitol	2.3	2.3	0.3	-2	-83	-17
Doxercalciferol	0.8	0.9	1.7	8	120	-11
Calcitriol	0.16	0.13	0.05	-17	-74	34
Antibiotics						
Daptomycin	0.097	0.217	0.129	123	-34	-10
Vancomycin	0.029	0.024	0.015	-18	-32	-9
Other drugs						
Levocarnitine	0.017	0.010	0.002	-43	-72	-29
Alteplase	0.023	0.020	0.003	-12	-87	-1

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.

**Epoetin beta was introduced to the U.S. market in 2015.

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

2011. By comparison, between 2010 and 2014, growth in total treatments (3 percent per year) was slightly higher than growth in the total number of beneficiaries (2 percent per year (data not shown)).

That the growth in total treatments in 2015 did not keep up with growth in the total number of beneficiaries may be partly associated with CMS's restatement (in the rule-making process) of its policy for paying for dialysis furnished more than thrice weekly. In the rule-making process, the agency stated that (1) some facilities have begun to offer dialysis modalities, such as home hemodialysis, where the standard treatment regimen is more than three treatments per week, and (2) there was variation among the Medicare administrative contractors in processing claims for these modalities, resulting in payment of more than thrice-weekly treatment without medical justification. CMS clarified that facilities must provide medical justification to be paid for furnishing

more than three dialysis treatments per week. The agency also said that the choice of dialysis modalities that require more than three treatments per week (including peritoneal dialysis and short frequent hemodialysis) does not constitute medical justification (Centers for Medicare & Medicaid Services 2014b).

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 2007 use data, we examined changes between 2007 and 2015 (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 2014 and between 2014 and 2015.

The dialysis PPS increased the incentive for providers to be more judicious in providing dialysis drugs since those 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.

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 the two ESAs marketed during this period declined—epoetin alfa by 45 percent and darbepoetin alfa by 40 percent (Table 6-5). 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 morbidity and mortality, which resulted in the Food and Drug Administration changing the ESA label in 2011.

Between 2014 and 2015, 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 two drugs increased between 2014 and 2015: use of calcitriol, a vitamin D agent, increased by 34 percent (from 0.03 mcg to 0.05 mcg per treatment) and use of darbepoetin alfa, an ESA, increased by 81 percent (from 0.75 mcg to 1.36 mcg per treatment (Table 6-5)). Despite the increase in calcitriol and darbepoetin alfa, use across all vitamin D agents and ESAs declined between 2014 and 2015 (as measured by multiplying drug units per treatment reported on 2014 and 2015 claims by each drug's 2016 average sales price).

Under the outpatient dialysis PPS payment bundle, there has been increased competition and some shifts in the use of drugs within the ESA and vitamin D therapeutic classes. Our preliminary analysis of ESA utilization since 2013 suggests that providers are switching beneficiaries from epoetin alfa to darbepoetin alfa or epoetin beta. Between 2013 and 2015, the number of beneficiaries who received only epoetin alfa declined by 40 percent (to roughly 200,000 beneficiaries) and the number of darbepoetin alfa users more than tripled (to about 70,000 beneficiaries). Our preliminary analysis also shows that in 2015, there were about 90,000 beneficiaries who received epoetin beta (which was introduced to the U.S. market in 2015). One of the LDOs announced its intent to have 71 percent of the company's ESA patients (110,000 patients) switched to epoetin beta (from epoetin alfa) by the end of the first quarter of 2016 (Reuters 2016). In our 2016 report to the Congress, we discussed the increased competition

between the two principal vitamin D agents and the change in prescribing patterns of these two products (Medicare Payment Advisory Commission 2016).

Quality of care

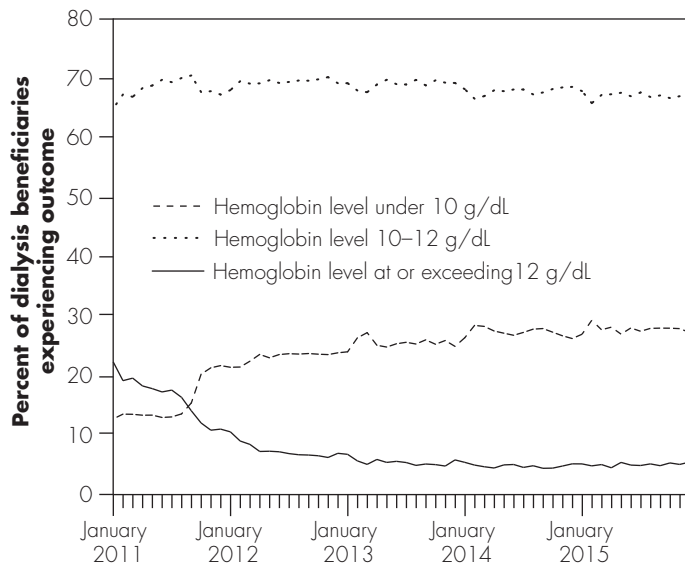
Our analysis focuses on changes in quality indicators—including mortality and morbidity, process measures that assess dialysis adequacy and anemia management, and treatment utilization (home dialysis and kidney transplantation rates)—between 2011, the first year of the outpatient dialysis PPS, and 2015. The analysis, except where indicated, is based on the Commission's analysis of Medicare FFS enrollment and claims data between 2011 and 2015, CMS's monthly monitoring data (Centers for Medicare & Medicaid Services 2014a), and data from the U.S. Renal Data System (USRDS).

From 2011 to 2015, unadjusted mortality, hospitalization, and readmission rates declined while unadjusted emergency department (ED) use rose modestly. 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 in 2014 and 2015 because of a shortage of the solutions needed for the predominant home method, peritoneal dialysis (PD). The negative cardiovascular outcomes associated with high ESA use generally declined, and blood transfusion use, which initially increased under the PPS, declined in 2014 and 2015.

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 Medicare spending, and demand far outstrips supply. We also discuss CMS's new payment model—the ESRD Comprehensive Care Initiative—that 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

According to the Commission's analysis of claims data, between 2011 and 2015, mean all-cause hospital stays per beneficiary declined from 1.7 admissions per beneficiary to 1.5 admissions per beneficiary, respectively. This finding is consistent with the trend of declining inpatient admissions

**FIGURE
6-2****Changes in hemoglobin
levels, 2011–2015**

Note: Data are compiled on a monthly basis by CMS.

Source: MedPAC analysis of 2011–2015 claims submitted by dialysis facilities.

for all Medicare FFS beneficiaries during this period. In addition, USRDS data shows that admission rates also fell for ESRD-related complications and comorbidities between 2010 and 2014 (United States Renal Data System 2016).⁷ During this period, 30-day readmission rates also declined, from 23 percent to 21 percent, respectively, and unadjusted annual rates of mortality declined from 16 percent of dialysis beneficiaries to 15 percent. According to CMS’s and the Commission’s analyses, the proportion of dialysis beneficiaries who used the ED increased modestly from an average of 10.5 percent per month in 2011 to 11.5 percent per month in 2015.

Beneficiaries’ fluid management is related to factors such as the adequacy of the dialysis procedure and dietary management. According to the Commission’s analysis, between 2011 and 2015, from 96 percent to 97 percent of hemodialysis beneficiaries and 88 percent to 92 percent of peritoneal dialysis beneficiaries received adequate dialysis, defined as having enough waste removed from their blood. Between 2011 and March 2015, 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 (Centers for Medicare & Medicaid Services 2014a).

Process and health outcome measures reflect the change in anemia management under the PPS. Anemia is measured by a blood test to check the level of hemoglobin, the protein that carries oxygen in red blood cells. According to the Commission’s analysis, from 2011 to 2015, median hemoglobin levels fell from 11.1 g/dL to 10.5 g/dL. Figure 6-2 shows that 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). The proportion of beneficiaries receiving a blood transfusion increased during the first two years of the PPS (2011 and 2012) from 3.2 to 3.4 percent per month, respectively (Centers for Medicare & Medicaid Services 2014a). However, according to CMS’s and the Commission’s analysis, between 2013 and 2015, the rate of blood transfusions declined from 3.2 percent to 2.6 percent of beneficiaries per month, respectively.⁸ The cumulative share of beneficiaries experiencing negative cardiovascular outcomes—stroke, acute myocardial infarction, and heart failure—associated with earlier higher ESA use (before 2011) generally declined (Centers for Medicare & Medicaid Services 2014a).

Two recently published studies found similar effects of the new outpatient dialysis PPS and the change in the Food and Drug Administration’s ESA label on the outcomes of anemia management (Chertow et al. 2016, Wang et al. 2016). Based on a study population of incident (new) hemodialysis beneficiaries treated between January 2008 and June 2013, Wang and colleagues found that after the dialysis PPS was implemented, the rate of blood transfusions modestly increased but the risk of major adverse cardiovascular events and mortality were unchanged, and the risk of stroke significantly declined. In addition, Wang and colleagues also found that the risk of major adverse cardiovascular events and death for African American patients was significantly reduced. Based on a study population of dialysis beneficiaries treated between 2005 and 2012, Chertow and colleagues (2016) reported that rates of all-cause and cause-specific mortality declined as expected on the basis of secular trends, while rates of stroke, venous thromboembolic disease, and heart failure were lower than expected in 2012.

As discussed in our June 2014 report, clinical process measures may exacerbate the incentives in FFS to overprovide and overuse services (Medicare Payment Advisory Commission 2014b). For example, before 2011, targeting higher hemoglobin levels was associated

with higher ESA use among dialysis beneficiaries. 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. Clinical outcomes, such as rates of stroke, are a better indicator of anemia management in the dialysis population. The Commission has stated that Medicare should transition over the next decade to a quality measurement system that uses a small number of population-based outcome measures (Medicare Payment Advisory Commission 2014b).

According to CMS’s and the Commission’s analyses, between 2011 and 2015, the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.9 percent to 10.6 percent (Centers for Medicare & Medicaid Services 2014a). While we are encouraged by this modest increase, differences by race persist: African Americans are less likely to use home methods. According to the Commission’s analysis, African Americans account for 27 percent of home dialysis beneficiaries compared with about 36 percent of all dialysis beneficiaries.

Beginning around 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. The proportion of beneficiaries dialyzing at home remained steady between September 2014 and December 2015, ranging from a monthly average of 10.5 percent to 10.7 percent. The supply shortage resulted 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). Although steps have been taken to increase the supply of PD solutions, the limitation on the number of new PD patients held through the end of 2015 (Baxter 2016).⁹

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. In addition,

**TABLE
6-6**

**Between 2011 and 2015,
the number of kidney transplants
increased, and African Americans
and Hispanics accounted for
an increasing share**

	2011	2015
Total transplants	16,816	17,878
Share of live donors	34%	31%
Share of:		
Whites	52	46
African Americans	26	28
Hispanics	15	17
Asians	6	6
Others	2	2

Note: Totals may not sum to 100 percent due to rounding.

Source: United Network for Organ Sharing. 2016. National data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.

transplantation results in lower Medicare spending; in 2014, average Medicare spending for patients who had a functioning kidney transplant or received a kidney transplant was substantially lower than spending for dialysis patients (\$34,559 vs. \$90,143, respectively) (United States Renal Data System 2016). 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 education for patients; clinician referral for transplant evaluation at a transplant center; and transplant center policies.

Between 2011 and 2015, according to the United Network for Organ Sharing, the number of kidney transplants increased in aggregate by 6 percent to 17,878 (United Network for Organ Sharing 2016). In 2015, African Americans were less likely than White patients to receive kidney transplants despite their threefold greater likelihood of developing ESRD; however, between 2011 and 2015, African Americans accounted for an increasing share of total transplants (Table 6-6). According to Ephraim and colleagues (2012), the lower rates of kidney transplantation for African Americans compared

with other groups 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 their treatment options and managing the disease and related comorbidities, MIPPA established Medicare payment for up to six sessions of kidney disease education (KDE) per beneficiary. Since its implementation, relatively few beneficiaries have been provided KDE services. About 3,400 beneficiaries were provided such services in 2014 and 2015 compared with about 2,900 beneficiaries in 2013 and about 4,200 beneficiaries in 2011 and in 2012. Medicare KDE spending in 2015 was about \$500,000.¹⁰

Education efforts directed at patients can be effective in encouraging them to make an informed decision about their treatment, including home dialysis, in-center dialysis, and conservative care. For example, a recent review of educational interventions found a strong association between patient-targeted dialysis modality education and choosing and receiving PD (Devoe et al. 2016). 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 service's 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.¹¹ 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 CKD (i.e., ESRD) but who have not started dialysis and individuals who have already initiated hemodialysis, might also benefit from Medicare KDE 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. Under the authority of the Center for Medicare & Medicaid

Innovation, the first round of the Comprehensive ESRD Care (CEC) 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. The second round of the CEC model began in 2017.

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 ESCOs participating in round 1, 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 1 ESCO is operated by a small dialysis organization (Rogosin Institute), which operates fewer than 200 dialysis facilities. For the first performance year, the CEC model has approximately 16,000 beneficiaries associated with the 13 ESCOs.

In the first round of the CEC Initiative, the ESCOs operated by the three large dialysis organizations were held to two-sided risk-based payment, while the one small dialysis organization was held to one-sided risk-based payment. (Under two-sided risk, the provider is at financial risk if specified goals are not achieved but is rewarded if the goals are met. Under one-sided risk, the provider is not penalized financially if goals are not met.) The initial agreement period lasts for three years; thereafter, CMS and the ESCOs have the option of extending the agreement for an additional two years based on the ESCOs' performance. A summary of selected features of the model that includes beneficiary attribution and the calculation of shared savings can be found in the Commission's March 2016 report to the Congress. In May 2016, CMS announced a new solicitation for a second round of participants (for payment year 2). The additional 24 ESCOs accepted through the second application round began in January 2017. For the second payment year, CMS has added an optional two-sided risk payment option (in addition to a one-sided payment track) for small dialysis organizations.

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 CEC initiative, dialysis beneficiaries in selected geographic areas also have access to ESRD special needs plans (SNPs). Between November 2015 and 2016, there was a modest increase in ESRD SNP enrollment and the number of ESRD SNPs. As of November 2016, about 3,500 dialysis beneficiaries were enrolled in 10 SNPs operated by 4 managed care organizations in 6 states (Arizona, California, Colorado, Nevada, North Carolina, and Texas). By comparison, as of November 2015, 2,700 dialysis beneficiaries were enrolled in 5 SNPs operated by 3 managed care organizations in California and in Nevada. While the CEC 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 Quality Incentive Program (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 a second quality system necessary 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 LDOs, as well as other renal companies, appear to have had adequate access to capital in 2016. For example, in 2016:

- DaVita formed a joint venture with New York's largest health care provider, Northwell Health, to provide integrated kidney care to patients in Queens and Long

Island (Northwell Health 2016). In addition, DaVita acquired two physician groups—Family Health Care of Central Florida, a primary care group with 13 providers in Orlando, and Mountain View Medical Group, a physician group in Colorado Springs. Internationally, the company signed a joint venture agreement with an investment fund to collectively own a portion of DaVita's Asia-Pacific kidney care business.

- Fresenius announced plans to provide integrated health care management for patients with renal disease who are enrolled in one of seven Medicare Shared Savings Program accountable care organizations operated by Collaborative Health Systems and physician partners (*Business Wire* 2016). Fresenius entered into a joint venture partnership with MemorialCare Health System, an integrated delivery system, to operate 15 dialysis clinics in Orange and Los Angeles counties. Frenova Renal Research, a subsidiary of Fresenius Medical Care North America, opened a new office location in North Carolina and expanded its U.S. field-based staff in Florida, Illinois, Louisiana, New York, and North Carolina. Fresenius established a subsidiary (Unicyte AG) focusing on regenerative medicine. Internationally, the company purchased a Spanish hospital group for 5.76 billion euros (\$6.42 billion) in its largest acquisition as it seeks to expand its German network across Europe.
- U.S. Renal Care announced that it is partnering with Liberty Administrative Services to share ownership and management responsibilities at nine Dallas-area dialysis clinics previously managed by Liberty Administrative Services. The clinics serve more than 500 patients.
- Nonprofit dialysis provider Satellite Healthcare acquired three dialysis centers in Laredo, Texas, from DSI Renal.

Providers' access to capital can be affected by factors such as nongovernment and government investigations and legal claims. In August 2016, CMS began investigating whether dialysis facilities and other providers have been steering patients eligible for or receiving Medicare, Medicaid, or both into individual market plans under the Affordable Care Act (Centers for Medicare & Medicaid Services 2016). Subsequently, one dialysis organization announced that it would

suspend support for applications for charitable premium assistance by patients enrolled in minimum essential Medicaid coverage who are seeking additional coverage from a 2017 Affordable Care Act plan (DaVita 2016). In addition, in July 2016, a large commercial payer filed a lawsuit in U.S. District Court alleging that a midsized publicly traded dialysis organization switched patients from Medicare and Medicaid coverage to plans operated by the commercial payer (Mathews 2016).

In public financial filings, both LDOs reported positive financial performance for 2015, including strong organic volume and revenue growth—that is, growth achieved apart from mergers and acquisitions. Since 2010, the two largest dialysis organizations have grown through large acquisitions and mergers of other dialysis facilities and other health care organizations. For example, during this period, both large dialysis organizations acquired midsized for-profit organizations: DaVita acquired DSI Renal and Fresenius acquired Liberty Dialysis. In addition, both organizations acquired large physician services organizations: DaVita purchased HealthCare Partners, which was at the time the largest operator of physician groups and networks, and Fresenius became a majority shareholder in Sound Physicians and acquired Cogent Healthcare.

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 2015 and examined trends in spending under the PPS. We also reviewed evidence regarding providers' costs under the PPS.

Medicare payments for outpatient dialysis services

In 2014 and 2015, Medicare spending for outpatient dialysis services remained relatively flat at \$11.2 billion in both years. Per capita spending decreased by 1.2 percent, from about \$29,200 to \$28,850. The decline in per capita spending reflects two factors: (1) a statutory update of 0 percent in 2015 and (2) a decline (by about 0.8 percent) between 2014 and 2015 in the number of dialysis treatments per beneficiary.

Part D spending for dialysis drugs

Under the dialysis PPS, 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 2014 (the most recent year data are available), Part D spending for two categories of dialysis drugs (calcimimetics and phosphate binders) totaled \$1.5 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.¹² In addition, between 2011 and 2014, Part D spending for dialysis drugs grew more rapidly than Part D spending for dialysis beneficiaries (22 percent vs. 15 percent, respectively). In 2014, Part D spending for dialysis drugs constituted 55 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. However, the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 delayed bundling these drugs until 2025. Nevertheless, if an injectable equivalent (or form of administration other 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. One study that analyzed changes in processes of care under the PPS reported that use of calcimimetics and phosphate binders by small dialysis organizations increased under the PPS (Brunelli et al. 2013).¹³ The decision-making process would be based on what is best for the patient. Giving the Secretary the flexibility to rebase the payment bundle after the oral-only dialysis drugs are included in the dialysis PPS payment bundle might lead to savings for beneficiaries and taxpayers.

In addition, including Part D dialysis drugs in the Part B PPS payment bundle might lead to improving the value of Medicare spending and more price competition:

- Including cinacalcet, which is prescribed to treat secondary hyperparathyroidism that can result from loss of kidney function, in the Part B PPS payment bundle could lead to efficiencies in the delivery of quality care. Based on results of a multicenter, prospective, randomized placebo-controlled trial, some clinicians concluded that the routine use of cinacalcet may not be warranted (Palmer et al. 2013).¹⁴ Between 2013 and 2014, Part D spending for cinacalcet grew by 21 percent to \$563 million in 2014.
- Multiple phosphate binders are marketed in the United States, and including them in the Part B payment bundle might increase price competition among the available products. According to researchers, the choice of which phosphate binder to prescribe is dependent on “physician preference, cost, reimbursement issues, tolerability, side effects, patient adherence, and other factors” (Nguyen et al. 2016). Palmer and colleagues (2016), in a recent meta-analysis of phosphate binders in patients with CKD, found no significant differences in all-cause mortality between any single agent versus placebo and concluded that “the failure of any agent to reduce mortality versus placebo suggests that a less aggressive approach to phosphate-lowering treatment may be entirely appropriate in all patients pending the availability of new evidence” (Palmer et al. 2016). Between 2013 and 2014, Part D spending for phosphate binders increased by 24 percent to \$980 million.

Providers’ costs for outpatient dialysis services under the outpatient dialysis PPS

To assess the appropriateness of costs for dialysis services paid for under the dialysis 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 2014 and 2015 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 varied by cost category

Between 2014 and 2015, the cost per treatment rose by 0.5 percent, from about \$243 per treatment to \$244 per treatment. During this period, the cost per treatment for ESAs and other Part B injectable drugs that were separately billable before 2011 each declined by 6

percent. Together, these two cost categories accounted for 13 percent of the total cost of treatment in 2015. The cost per treatment decline for ESAs and other injectable drugs somewhat offset increases in the other major cost categories:

- Labor costs, which accounted for about 30 percent of the cost per treatment, increased by 2 percent.
- Administrative and general expenses and capital costs, which accounted for 25 percent and 16 percent of the cost per treatment, respectively, each increased by 1 percent.
- Supply costs, which accounted for about 10 percent of the cost per treatment, increased by 3 percent.

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 2014 and 2015, per treatment costs decreased by 4.7 percent for facilities in the 25th percentile of cost growth and increased by 3.7 percent for facilities in the 75th percentile.

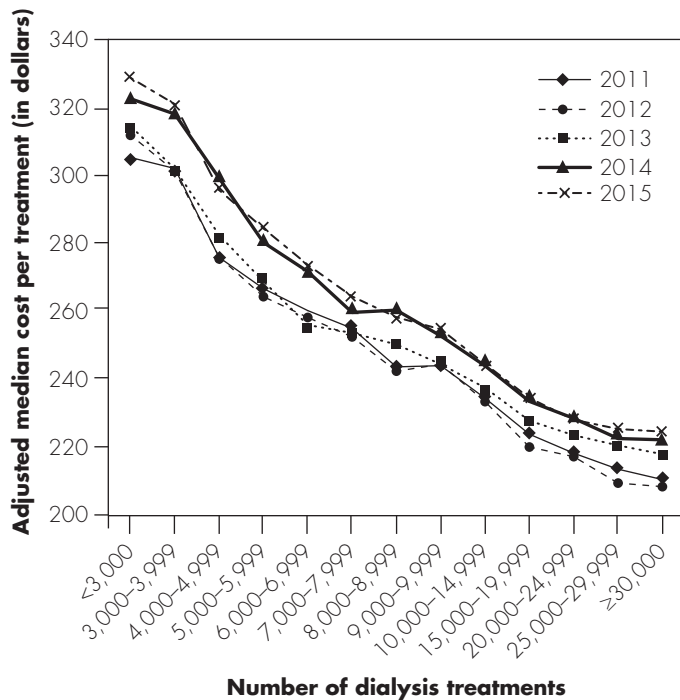
It is unknown the extent to which some of the variation in costs among facilities is due to differences in the accuracy of the data that facilities report. In 2014 and 2015, we found substantial variation in the level of selected cost categories reported by the five leading dialysis organizations (as measured by the total number of facilities). For example, the cost per treatment for administrative and general services differed by roughly \$25 among these organizations. We anticipate that CMS’s audit of a representative sample of ESRD cost reports will examine the accuracy of facilities’ cost reports.

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 2015, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-3, p. 176). That is, the greater the facility’s service volume, the lower its cost per treatment. Facilities that qualified for increased Medicare payment due to low volume had substantially higher cost per treatment for capital and administrative and general services compared with all other facilities.

FIGURE 6-3

Higher volume dialysis facilities have lower cost per treatment, 2011–2015



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 2011–2015 cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

Medicare margin for freestanding facilities in 2015

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 2015. For 2015, we estimate that the aggregate Medicare margin was 0.4 percent (Table 6-7). Margins decidedly vary by treatment volume. In 2015, facilities in the lowest volume quintile had margins at or below –16.9 percent, and facilities in the top volume quintile had margins of 6.5 percent or greater.

Urban facilities had higher margins than rural facilities (1.3 percent and –5.1 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 total treatments provided. In 2015, urban facilities

averaged 12,229 treatments, while rural facilities averaged 7,778 treatments (data not shown).

In evaluating the adequacy of payments, it is also important 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. In contrast, 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 16.6 percent, suggesting facilities with available capacity have an incentive to treat Medicare beneficiaries. This margin is a positive indicator of patient access.

Projecting the Medicare margin for 2017

The aggregate Medicare margin for 2017 is projected to be –1.0 percent. This projection considers provider cost growth between 2014 and 2015 and the following policy changes that went into effect between 2015 (the year of our most recent margin estimates) and 2017:

- The Protecting Access to Medicare Act of 2014 (PAMA) mandated that the base payment rate be rebased in 2016 and 2017 to account for the reduced drug utilization under the dialysis PPS. This rebasing adjustment reduced the statutory update (based on the ESRD market basket offset by a productivity adjustment) by 1.25 percent in each year. The net payment update was 0.15 percent in 2016 and will be 0.55 percent in 2017.

**TABLE
6-7**

Medicare margins in 2015 varied by type of freestanding dialysis facility

Provider type	Medicare margin	Percent of freestanding dialysis facilities	Percent of freestanding dialysis facility treatments
All	0.4%	100%	100%
Urban	1.3	80	87
Rural	-5.1	20	13
Treatment volume (quintile)			
Lowest	-16.9	20	7
Second	-8.8	20	12
Third	-2.8	20	17
Fourth	2.3	20	24
Highest	6.5	20	39

Note: Totals may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from 2015 cost reports and outpatient claims submitted by facilities to CMS and the 2015 Dialysis Compare database.

- Other regulatory changes are expected to result in increased payments in 2017 of 0.18 percent.
- Payments will be reduced by 0.17 percent and 0.13 percent, respectively, due to the ESRD QIP in 2016 and 2017.
- The sequester, which is now fully reflected in Medicare’s payments to providers, reduced Medicare payments to providers by 2 percent beginning April 2013.
- A regulatory change beginning in 2016 eliminated the limit on the medical director compensation that facilities can report on their cost reports. Before 2016, Medicare imposed a limit on the amount of compensation that could be reported on facilities’ cost reports, which was based on the Reasonable Compensation Equivalent limit for a board-certified physician of internal medicine (for a metropolitan area of greater than one million people) of \$197,500.¹⁵ This regulatory action essentially changed the definition of a Medicare-allowable cost that facilities can report on their cost report. If the limit on the reporting of medical director fees had not been eliminated in 2016, then the aggregate 2017 projected margin would be roughly the same as our estimate of the margin for 2015 (0.4 percent).

How should Medicare payments change in 2018?

For 2018, PAMA 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 a rebasing adjustment of 1 percentage point. Based on CMS’s latest forecast of changes in the ESRD market basket costs for calendar year 2018 (2.2 percent), the update to the 2018 payment rate would be 0.7 percent. In addition to this statutory provision, the ESRD QIP is expected to decrease total payments by 0.14 percent in 2018.

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.

RECOMMENDATION 6

The Congress should increase the outpatient dialysis base payment rate by the update specified in current law for calendar year 2018.

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 0.4 percent in 2015 and is projected to be -1.0 percent in 2017.

IMPLICATIONS 6

Spending

- In 2018, the statute sets the payment update at the market basket, net of the productivity adjustment and a rebasing adjustment of 1 percentage point. 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. ■

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 The 21st Century Cures Act lifts the prohibition on ESRD beneficiaries enrolling in MA beginning in 2021.
- 4 Age groups are 21 years and younger, 22 to 44 years, 45 to 64 years, 65 to 74 years, and 75 years and older.
- 5 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.
- 6 These drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the new payment method.
- 7 Between 2011 and 2014, adjusted hospitalization rates (per patient-year) for hemodialysis patients fell from 0.5 to 0.4 admissions for cardiovascular and infection events and from 0.2 to 0.1 admissions for vascular access events. Adjusted admission rates (per patient-year) for PD patients also declined for these ESRD-related complications and comorbidities during this period (United States Renal Data System 2016).
- 8 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 for 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 to receive a transplant.
- 9 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 2015, Zumoff 2015).
- 10 This analysis used 100 percent of carrier and outpatient claims submitted for KDE services from 2011 through 2015.
- 11 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.
- 12 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.
- 13 Between the fourth quarter of 2010 and the second quarter of 2011, use of cinacalcet increased from 19 percent to 27 percent of beneficiaries, and use of phosphate binders increased from 56 percent to 68 percent of beneficiaries (Brunelli et al. 2013).
- 14 The Evaluation of Cinacalcet Hydrochloride Therapy to Lower Cardiovascular Events trial—a multicenter, prospective, randomized, placebo-controlled trial—found that cinacalcet did not significantly reduce the risk of death or major cardiovascular events in patients with moderate to severe secondary hyperparathyroidism undergoing dialysis (Chertow et al. 2012).
- 15 Following audits by the Office of Inspector General and the Medicare administrative contractors in the 1980s that showed instances in which freestanding facilities compensated their medical directors and administrators excessively, CMS set limits for reasonable compensation when reporting medical director fees on dialysis facility cost reports. CMS discarded the limit based on the notion that limits are generally used when determining payment for providers that are reimbursed on a reasonable cost basis and are typically not used in PPSs that update payment rates using market basket methods.

References

- Baxter. 2016. PD supply. <http://www.homebybaxter.com/how/pdsupplyupdate.html>.
- Baxter. 2014. Letter from Richard Marritt, Region Head and General Manager, U.S. 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).
- Brunelli, S. M., K. L. Monda, J. M. Burkart, et al. 2013. Early trends from the Study to Evaluate the Prospective Payment System Impact on Small Dialysis Organizations (STEPPS). *American Journal of Kidney Diseases* 61, no. 6 (June): 947–956.
- Business Wire*. 2016. Universal American ACOs and Fresenius Medical Care partner to improve health of end stage renal disease patients. <http://www.businesswire.com/news/home/20161026005423/en/Universal-American-ACOs-Fresenius-Medical-Care-Partner>.
- Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. CMS examines inappropriate steering of people eligible for Medicare or Medicaid into marketplace plans. Press release. August 18. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-18-2.html>.
- 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. 2014a. *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. 2014b. Medicare program; end-stage renal disease prospective payment system, quality incentive program, and durable medical equipment, prosthetics, orthotics, and supplies. Final rule. *Federal Register* 79, no. 215 (November 6): 66120–66265.
- Chertow, G. M., G. A. Block, R. Correa-Rotter, et al. 2012. Effect of cinacalcet on cardiovascular disease in patients undergoing dialysis. *New England Journal of Medicine* 367, no. 26 (December 27): 2482–2494.
- Chertow, G. M., J. Liu, K. L. Monda, et al. 2016. Epoetin alfa and outcomes in dialysis amid regulatory and payment reform. *Journal of the American Society of Nephrology* 27, no. 10 (October): 3129–3138.
- Cooper, B. A., P. Branley, L. Bulfone, et al. 2010. A randomized, controlled trial of early versus late initiation of dialysis. *New England Journal of Medicine* 363, no. 7 (August 12): 609–619.
- DaVita. 2016. DaVita announces changes to Medicaid patients seeking Affordable Care Act plan coverage. Press release. October 31. <http://pressreleases.davita.com/2016-10-31-DaVita-Announces-Change-for-Medicaid-Patients-Seeking-Affordable-Care-Act-Plan-Coverage>.
- Devoe, D. J., B. Wong, M. T. James, et al. 2016. Patient education and peritoneal dialysis modality selection: A systematic review and meta-analysis. *American Journal of Kidney Diseases* 68, no. 3 (September): 422–433.
- 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.
- Evans, M., G. Tettamanti, O. Nyren, et al. 2011. No survival benefit from early-start dialysis in a population-based, inception cohort study of Swedish patients with chronic kidney disease. *Journal of Internal Medicine* 269, no. 3 (March): 289–298.
- Fresenius Medical Care. 2015. Fresenius Medical Care’s Knoxville manufacturing plant on schedule to help ease nationwide shortage of peritoneal dialysis solution. Press release. November 5. <http://newsroom.fmna.com/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.
- Kazmi, W. H., D. T. Gilbertson, G. T. Obrador, et al. 2005. Effect of comorbidity on the increased mortality associated with early initiation of dialysis. *American Journal of Kidney Diseases* 46, no. 5 (November): 887–896.
- Mathews, A. W. 2016. UnitedHealth sues American Renal Associates, alleging fraud. *Wall Street Journal*, July 1.
- Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
- 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. 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.
- Nguyen, T., T. Pham, and T. Huynh. 2016. Phosphate binder choices used in ESRD patients. *Nephrology News & Issues*, July.
- Northwell Health. 2016. DaVita, Northwell Health announce joint venture to deliver full suite of kidney care services. Press release. May 19. <https://www.northwell.edu/about/news/davita-northwell-health-announce-joint-venture-deliver-full-suite-kidney-care-services-0>.
- Palmer, S. C., S. Gardner, M. Tonelli, et al. 2016. Phosphate-binding agents in adults with CKD: A network meta-analysis of randomized trials. *American Journal of Kidney Diseases* 68, no. 5 (November): 691–702.
- Palmer, S. C., I. Nistor, J. C. Craig, et al. 2013. Cinacalcet in patients with chronic kidney disease: A cumulative meta-analysis of randomized controlled trials. *PLoS Medicine* 10, no. 4: e1001436.
- Rettig, R. A., and N. G. Levinsky. 1991. *Kidney failure and the federal government*. Washington, DC: National Academy of Sciences.
- Reuters. 2016. FMC aims for 110,000 U.S. patients to be on Mircera in first-quarter. February 24. <http://www.reuters.com/article/us-fresenius-medi-results-mircera-idUSKCN0VX11F>.
- Seaborg, E. 2015. Peritoneal dialysis fluid shortage disrupted growth of popular therapy. *Kidney News*, March.
- Stel, V. S., F. W. Dekker, D. Ansell, et al. 2009. Residual renal function at the start of dialysis and clinical outcomes. *Nephrology Dialysis Transplantation* 24, no. 10 (October): 3175–3182.
- Traynor, J. P., K. Simpson, C. C. Geddes, et al. 2002. Early initiation of dialysis fails to prolong survival in patients with end-stage renal failure. *Journal of the American Society of Nephrology* 13, no. 8 (August): 2125–2132.
- United Network for Organ Sharing. 2016. National data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.
- United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2016. *USRDS 2016 annual data report*. Bethesda, MD: NIDDK.
- Wang, C., R. Kane, M. Levenson, et al. 2016. Association between changes in CMS reimbursement policy and drug labels for erythrocyte-stimulating agents with outcomes for older patients undergoing hemodialysis covered by fee-for-service Medicare. *JAMA Internal Medicine* (October 24).
- Zumoff, R. 2015. Fresenius partners with Swiss device maker to build new peritoneal dialysis machines. *Nephrology News & Issues*, November 3.

