CHAPTER 5

Outpatient dialysis services

RECOMMENDATION

5 For calendar year 2025, the Congress should update the 2024 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

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

CHAPTER 5

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat most individuals with end-stage renal disease (ESRD). In 2022, about 290,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 7,800 dialysis facilities. In 2022, FFS Medicare expenditures for outpatient dialysis services totaled $8.8 billion.

Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, and access to capital. The 2022 aggregate FFS Medicare margin was below zero due to the growth of providers' cost per treatment, particularly labor and capital costs, which outpaced the growth in the ESRD prospective payment system (PPS) payment per treatment.

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 that access to dialysis services remains adequate.

- ***Capacity and supply of providers—***The capacity of dialysis facilities appears to exceed demand. Between 2021 and 2022, the number of in-center treatment stations was steady while the number of Medicare

In this chapter

beneficiaries on dialysis (in both FFS Medicare and Medicare Advantage (MA)) declined (which is partly linked to the excess mortality experienced by ESRD patients during the coronavirus pandemic), and the share of total treatments furnished by freestanding dialysis facilities in the home continued to increase.

- ***Volume of services*—**The 14 percent decline in FFS treatments provided in 2022 is largely due to the shift of beneficiaries on dialysis from FFS Medicare to MA, following the removal of a statutory provision that had prevented most dialysis beneficiaries from enrolling in MA plans. Between January 2021 and December 2022, the share of dialysis beneficiaries enrolled in FFS Medicare fell from 64 percent to 53 percent. At the same time, the per treatment use of ESRD drugs in the payment bundle (particularly erythropoiesis-stimulating agents used in anemia management) has continued to decline since 2010.
- ***FFS Medicare marginal profit*—**An estimated 18 percent marginal profit in 2022 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries.

***Quality of care*—**FFS dialysis beneficiaries' rates of all-cause hospitalization, emergency department use, and mortality held relatively steady between 2021 and 2022. The share of beneficiaries dialyzing at home, which is associated with better patient satisfaction, continued to grow.

***Providers' access to capital*—**Information from investment analysts suggests that access to capital for dialysis providers continues to be strong. Under the ESRD PPS, the two largest dialysis organizations have grown through acquisitions of and mergers with midsize dialysis organizations.

***FFS Medicare payments and providers' costs*—**Between 2021 and 2022, FFS Medicare payment per treatment in freestanding dialysis facilities (which provide the vast majority of FFS dialysis treatments) grew by 2 percent while cost per treatment rose by 6 percent. The increase in the cost per treatment is attributable to the growth in labor and capital costs in this period, which was substantially higher compared with these categories' historical cost growth. Consequently, the aggregate FFS Medicare margin fell from 2.3 percent in 2021 to –1.1 percent in 2022. We project a 2024 aggregate FFS Medicare margin of 0 percent.

How should FFS Medicare payments change in 2025?

Under current law, the FFS Medicare base payment rate for dialysis services is projected to increase by 1.8 percent in 2025. Given that our indicators of payment adequacy are generally positive, the recommendation is that, for calendar year 2025, the Congress update the 2024 ESRD PPS base payment rate by the amount determined under current law. ■

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. 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. By contrast, 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.

Each dialysis method has advantages and drawbacks; 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. 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 such advantages 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 (CKD) 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 ESRD drugs and biologics to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

In 2022, about 290,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare, while roughly 240,000 ESRD beneficiaries on dialysis were enrolled in Medicare Advantage (MA). About 7,865 dialysis facilities provided outpatient dialysis services to FFS beneficiaries on dialysis. The dialysis sector is highly consolidated, with two large dialysis organizations (LDOs)—Fresenius Medical Care and DaVita—dominating the industry. In 2022, these LDOs accounted for three-quarters of facilities and Medicare FFS treatments. Moreover, in 2022, the five largest dialysis organizations accounted for roughly 85 percent of facilities and Medicare FFS treatments.

Since 2011, FFS Medicare has been paying facilities using a prospective payment system (PPS) bundle that includes ESRD drugs (for which facilities previously received separate payments) and services (for which other Medicare providers, such as clinical laboratories, previously received separate payments).[1,2,3] In 2022, spending for outpatient dialysis services under the ESRD PPS was $8.8 billion. This total includes nearly $4.7 million in add-on payments associated with a new ESRD drug (Korsuva) and a new type of ESRD home hemodialysis equipment (Tablo Hemodialysis System). Additionally, in 2021 (the most recent data available), Part D spending for ESRD oral-only drugs that have not yet been included in the PPS—several phosphate binders—totaled $0.8 billion for FFS beneficiaries on dialysis.

TABLE 5–1

FFS beneficiaries on dialysis are disproportionately young, male, and Black compared with other Medicare FFS beneficiaries, 2022

	Share of FFS beneficiaries:	
	Dialysis beneficiaries	**Other beneficiaries**
Age		
Under 45 years	10%	3%
45–64 years	34	8
65–74 years	29	50
75–84 years	20	28
85+ years	7	10
Sex		
Male	57	47
Female	43	53
Race/ethnicity		
White	48	81
Black	31	8
Hispanic	8	3
Asian	5	3
All others	8	5
Residence, by type of county		
Urban	84	80
Micropolitan	9	11
Rural, adjacent to urban	5	5
Rural, not adjacent to urban	2	3
Frontier	1	1

Note: FFS (fee-for-service). "Other beneficiaries" excludes beneficiaries on dialysis and those who have received a kidney transplant. "Residence" reflects the beneficiary's county of residence in one of four categories (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the Urban Influence Codes. 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 enrollment data and claims submitted by dialysis facilities to CMS.

Characteristics of fee-for-service beneficiaries on dialysis, 2022

Compared with other Medicare FFS beneficiaries, FFS beneficiaries on dialysis are disproportionately younger, male, and Black (Table 5-1). In 2022, 73 percent of FFS dialysis beneficiaries were under 75 years old (with 44 percent under 65 years old), 57 percent were male, and 31 percent were Black. By comparison, among other FFS Medicare beneficiaries, 61 percent were under 75 years old (with 11 percent under 65 years old), 47 percent were male, and 8 percent were Black. A greater share of dialysis beneficiaries resided in urban areas compared with other FFS beneficiaries (84 percent vs. 80 percent).

FFS beneficiaries on dialysis are more likely to have full Medicaid benefits than all other FFS beneficiaries (39 percent vs. 13 percent). FFS Part D enrollees on dialysis

are more likely to receive the low-income subsidy than all other FFS Part D enrollees (65 percent vs. 26 percent). In addition, in 2021, FFS dialysis beneficiaries were less likely to have coverage from other sources, such as Medigap and employer-sponsored health plans (35 percent vs. 62 percent) and as likely to have no supplemental coverage (about 24 percent for each group in 2021).

Over the last decade, the adjusted rate of new ESRD cases, or incidence rate (which includes patients of all types of health coverage who initiate dialysis or receive a kidney transplant), has declined. Between 2011 and 2021 (the most recent year of data available), the adjusted incidence rate decreased by 1 percent per year, from 393 per million people to 366 per million people (United States Renal Data System 2023). This decline may be attributable to factors including better management of ESRD-related comorbidities but also to the excess mortality during the coronavirus pandemic. We estimate that about 66,000 FFS beneficiaries began dialysis in 2022 (a decline of nearly 7 percent compared with 2021).

Medicare pays for dialysis services under the ESRD 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.[4] 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. Indeed, many dialysis facilities are operated as joint ventures between dialysis organizations and physicians. Joint ventures allow participating partners to share in the management of dialysis facilities and in their profits and losses. Both the LDOs and midsize provider groups, including American Renal Associates and U.S. Renal Care, have established joint ventures with physicians.[5]

Medicare pays dialysis facilities for services provided to FFS beneficiaries under the ESRD PPS. Facilities are paid for a bundle of services provided during a single dialysis treatment, including ESRD drugs, laboratory tests, and other ESRD items and services.[6] For adult dialysis beneficiaries, the base payment rate does not differ by type of dialysis—in-center dialysis versus home dialysis—but rather by patient characteristics (age, body measurement characteristics, onset of dialysis, and selected acute and chronic comorbidities) and facility factors (low treatment volume, rural location, and local input prices).[7] Medicare pays facilities furnishing dialysis treatments in the facility or in a patient's home for up to three treatments per week, unless the additional dialysis treatments are reasonable and necessary and there is documented medical justification for more than three weekly treatments.

Under the ESRD PPS, Medicare also makes separate add-on payments in certain circumstances for new drugs, devices, and equipment.[8] CMS used a transitional drug add-on payment adjustment (TDAPA) to pay for new injectable calcimimetics from 2018 through 2020; in 2021, these drugs were included in the ESRD PPS's payment bundle. Currently, CMS pays a TDAPA for Korsuva (an antipruritic) through March 31, 2024, and for Jesduvroq (used to treat anemia) through September 2025.[9] CMS will apply a post-TDAPA payment for Korsuva beginning April 1, 2024, for three years. In 2022 and 2023, CMS used a transitional payment adjustment for new and innovative equipment and supplies (TPNIES) for the Tablo Hemodialysis System.[10] Unlike for ESRD drugs, a substantial clinical improvement standard is used to determine eligibility for a TPNIES add-on.[11]

Are FFS Medicare payments adequate in 2024?

To address whether payments for 2024 are adequate to cover the costs to efficiently provide care and determine how much providers' costs are likely to change in the update year (2025), we examine several indicators of payment adequacy. We assess beneficiaries' access to care by examining the capacity of dialysis facilities and changes over time in the volume of services provided. We also examine quality of care, providers' access to capital, and the relationship between Medicare's payments and facilities' costs. Most of our payment adequacy indicators for outpatient dialysis services are positive.

However, the aggregate FFS Medicare margin fell from 2.3 percent in 2021 to –1.1 percent in 2022 because cost growth (particularly for labor and capital services) outpaced payment growth. We project a 2024 FFS Medicare margin of 0 percent.

Beneficiaries' access to care: Indicators continue to be positive

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand, changes in the volume of services, and the marginal profitability of treating FFS Medicare dialysis beneficiaries under the PPS—shows that beneficiaries' access to care remains generally favorable.

Capacity has exceeded demand from dialysis patients across all insurance types

In 2022, there were 7,865 dialysis facilities nationwide. FFS Medicare accounted for 41 percent of all treatments furnished by providers.[12] Growth in the number of dialysis facilities and in-center treatment stations alongside growth in the number of dialysis beneficiaries suggests that, between 2018 and 2021, provider capacity exceeded FFS beneficiaries' demand for care. During that period, the number of facilities and their capacity to provide care—as measured by dialysis treatment stations—each grew by 2 percent annually (Table 5-2), compared with a 6 percent decline in the annual growth of the number of FFS dialysis beneficiaries (data not shown). In-center capacity during the period also exceeded demand from all dialysis patients, across all insurance types, not just FFS beneficiaries, as the number of dialysis patients of all types of health coverage grew 0.2 percent per year (data not shown) (United States Renal Data System 2023).

The number of facilities' in-center treatment stations grew more slowly between 2021 and 2022 compared with the annual growth from 2018 through 2021 (0.1 percent per year vs. 2 percent per year) but exceeded growth in the number of dialysis FFS or MA beneficiaries (which declined by 1 percent between 2021 and 2022). The slower growth of in-center capacity and the number of facilities from 2021 to 2022 compared with 2018 through 2021 may be attributable to factors including the following:

- The excess mortality among ESRD patients during the coronavirus pandemic and the decline (by 1 percent per year) in the incidence of ESRD during the past decade.
- The decline in total treatments (across all payers) and in-center treatments furnished by freestanding dialysis facilities. Between 2020 and 2022, total treatments declined by 1 percent per year and total in-center treatments declined by 2 percent per year.
- The increase in the use of home dialysis. Researchers have shown that the implementation of the ESRD PPS was associated with an increase in home dialysis use among patients starting dialysis (Lin et al. 2017).
- Recent facility closures by the two LDOs that together account for three-quarters of all treatments furnished in the U.S. The closures aim to optimize their facilities' capacity utilization that has been impacted by, for example, the increasing use of home dialysis and a decline in their patient census in some markets (DaVita 2022b). Both LDOs reported that most patients treated at a facility that closes receive care at another of the chain's clinics.
- The financial incentives associated with the Center for Medicare & Medicaid Innovation's (CMMI's) mandatory ESRD Treatment Choices (ETC) Model. This model rewards dialysis facilities and clinicians who are part of the model for increasing home dialysis use and kidney transplantation among adult dialysis beneficiaries and penalizes facilities and clinicians who do not.[13]

Our analysis of claims and enrollment data suggests that beneficiaries affected by facility closures between 2021 and 2022 obtained care elsewhere.

Based on data from Medicare claims, freestanding dialysis cost reports, and CMS's Dialysis Facility Compare database, 53 percent of facilities offered home dialysis in 2022, up from 50 percent in 2014. Among facilities that offered home dialysis, the share of total treatments furnished in the home rose from an average of 24 percent in 2014 to 30 percent in 2022.

For-profit, freestanding facilities provide most dialysis treatments: In 2022, freestanding facilities furnished 96 percent of FFS treatments, and for-profit facilities furnished 89 percent (Table 5-2). Between 2021 and 2022, capacity at freestanding and for-profit

TABLE 5–2

Increase in the number and capacity of freestanding and for-profit dialysis organizations but low growth between 2021 and 2022

	2022				Average annual percent change			
					Number of facilities		Number of stations	
	Total number of FFS treatments	Total number of facilities	Total number of stations	Mean number of stations	2018–2021	2021–2022	2018–2021	2021–2022
All	30.7 million	7,865	138,100	18	2%	–0.2%	2%	0.1%
	Share of total							
Freestanding	96%	95%	96%	18	2	0.1	2	0.3
Hospital based	4	5	4	14	–1	–5	–2	–5
Urban	86	84	87	18	2	0.1	2	0.4
Micropolitan	10	10	9	16	0.3	0	0.2	–0.1
Rural, adjacent to urban	3	4	3	14	–0.3	–2	0.2	–2
Rural, not adjacent to urban	1	2	1	12	–2	–2	–0.2	–2
Frontier	0.3	0.4	0.2	10	0	0	0.2	–1
For profit	89	89	90	18	2	0.2	2	1
Nonprofit	11	11	10	17	–1	–2	–0.4	–2
Two largest dialysis organizations	75	75	76	18	2	–0.2	2	–0.2
All others	25	25	24	17	1	0.4	0.3	2

Note: FFS (fee-for-service). Provider location reflects the county in which the provider is located, by county type (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban), based on an aggregation of the Urban Influence Codes. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

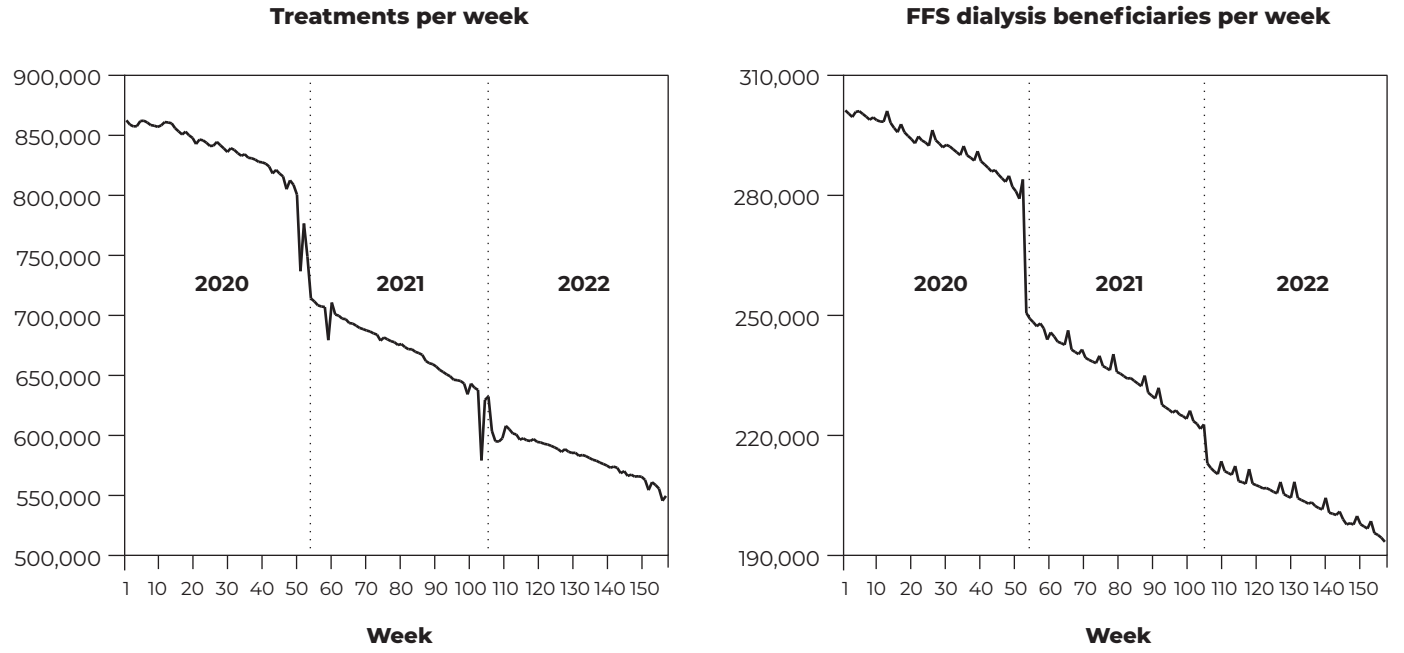
Source: Data compiled by MedPAC from the Dialysis Compare database from CMS and claims submitted by dialysis facilities to CMS.

facilities grew by 0.3 percent and roughly 1 percent, respectively, while capacity at hospital-based facilities fell by 5 percent, and capacity at nonprofit facilities fell by 2 percent.

The capacity of facilities in urban and rural areas in 2022 was generally consistent with where FFS beneficiaries on dialysis lived: 86 percent of FFS treatments were provided in urban areas and 87 percent of dialysis stations were located in urban areas. Between 2021 and 2022, capacity at urban facilities grew by 0.4 percent, while capacity at all rural facilities declined by 0.7 percent (data not shown). In June 2020, the Commission recommended that the Secretary replace the current low-volume payment adjustment and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment—to better protect isolated, low-volume dialysis facilities that are critical to ensuring beneficiary access. The Commission found that the facilities that would receive the LVI adjustment would be more appropriately targeted

FIGURE 5–1

Between 2020 and 2022, weekly number of FFS beneficiaries on dialysis and dialysis treatments declined



Note: FFS (fee-for-service). The decline between 2020 and 2021 in the weekly number of FFS beneficiaries and treatments is largely attributable to the coronavirus pandemic, which slowed the initiation of dialysis by new patients and caused excess mortality among beneficiaries with end-stage renal disease (ESRD). The decline since 2021 is largely attributable to enactment of the 21st Century Cures Act, which permitted beneficiaries with ESRD to enroll in Medicare Advantage plans starting in 2021. The variation in the weekly number of beneficiaries and treatments may be linked to seasonal factors.

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

compared with current policy (Medicare Payment Advisory Commission 2020).

Dialysis marginal profitability suggests that financial incentive to serve Medicare beneficiaries remains

Another measure of access is whether providers have a financial incentive to expand the number of Medicare beneficiaries they serve. In considering whether to treat a patient, a provider with excess capacity compares the 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 if it has the capacity to do so. In contrast, if payments do not cover the marginal costs, the provider could have a disincentive to care for Medicare beneficiaries.[14]

Medicare payments in 2022 exceeded dialysis facilities' marginal costs by 18 percent, a positive indicator of patient access in that facilities with available capacity have a financial incentive to treat Medicare beneficiaries.

Decline in the volume of FFS dialysis treatments reflects shift of beneficiaries on dialysis to Medicare Advantage

In 2020, the coronavirus pandemic slowed the initiation of dialysis by new patients and caused excess mortality

among patients with ESRD. As a result, the number of FFS beneficiaries on dialysis and FFS dialysis treatments provided each declined by 3 percent between 2019 and 2020. The decline in the number of FFS beneficiaries on dialysis and FFS treatments accelerated considerably in 2021 and 2022, after the enactment of the 21st Century Cures Act, which eliminated restrictions on MA enrollment for beneficiaries with ESRD (see text box on share of dialysis beneficiaries enrolled in MA, pp. 142–143).[15] As beneficiaries with ESRD shifted to MA in 2021 and 2022, the number of FFS beneficiaries on dialysis fell 13 percent per year, on average, and the number of FFS treatments fell 14 percent per year. Figure 5-1 shows the effect of both the pandemic and the statutory change on the weekly number of FFS dialysis beneficiaries and treatments. The effect of removing the statutory bar is highlighted by the roughly 8 percent drop in the number of FFS dialysis treatments in December 2020 and January 2021 and the additional 23 percent drop in FFS treatments furnished in January 2021 and December 2022. Some variation in the weekly number of beneficiaries and treatments is also linked to seasonal factors.[16]

Overall, in 2022, about 290,000 FFS beneficiaries on dialysis received 30.7 million dialysis treatments. Although FFS beneficiaries and treatments declined between 2021 and 2022, the number of dialysis treatments per beneficiary per week remained steady at 2.9 (data not shown).[17]

Use of most ESRD-related drugs has declined, with no sustained negative changes in beneficiaries' outcomes

Under the ESRD payment method used before 2011, certain ESRD-related 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. The Congress increased the incentive for dialysis providers to be more judicious in providing ESRD drugs by broadening the payment bundle in 2011 to include ESRD-related drugs that previously were billed separately. We examined changes between 2010 and 2022 (the most current year for which complete data are available) in the use per treatment for the leading ESRD drugs and aggregated them into four therapeutic classes: erythropoiesis-stimulating agents (ESAs), iron agents, bone and mineral metabolism agents (including vitamin D agents and the two calcimimetics, cinacalcet and etelcalcetide), and other products.[18]

As shown in Figure 5-3 (p. 144), most of the decline in the per treatment use of ESRD drugs occurred in the early years after ESRD drugs were included in the bundle. (For Figure 5-3, we estimated per treatment use by multiplying drug units per treatment reported on CMS claims by each drug's 2022 average sales price (ASP) plus 0 percent—i.e., holding price constant.[19]) For example, between 2010 and 2011, use per treatment across all therapeutic classes declined by 23 percent. Most of this decrease was due to declining ESA use, which also fell by 23 percent per year during the same period. Some of the decline in ESA use may 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. Although the ESRD PPS affected use of certain ESRD-related services, particularly the provision of drugs paid under the bundle, CMS has concluded that the agency's claims-based monitoring program has revealed no sustained negative changes in beneficiary health status (Centers for Medicare & Medicaid Services 2019).

Between 2021 and 2022, holding price constant, the use of all ESRD drugs in the four categories declined by 4 percent. This decline is linked to lower use of certain drugs in the ESA and bone and mineral metabolism categories (Table 5-3, p. 145). The Commission has reported a shift over time in the use of ESAs and vitamin D agents (paricalcitol, doxercalciferol, and calcitriol) due to price competition among the products within each category (Medicare Payment Advisory Commission 2022).

Quality of outpatient dialysis care is generally stable or improving for most measures

In 2021 and 2022, FFS dialysis beneficiaries' use of the emergency department (ED) and rates of hospitalization and mortality remained stable. Results of process measures that assess dialysis adequacy and anemia management (hemoglobin levels) and blood transfusion rates remained generally stable. Use of home dialysis and the number of kidney transplants increased during this period.[20]

Since 2021, the share of beneficiaries on dialysis enrolling in Medicare Advantage plans has accelerated

Historically, Medicare beneficiaries with end-stage renal disease (ESRD) generally had traditional fee-for-service (FFS) coverage because they were prohibited from enrolling in Medicare Advantage (MA) plans. However, beneficiaries who enrolled in a managed care plan before being diagnosed with ESRD could stay in the plan after they were diagnosed. Over time, the share of dialysis beneficiaries enrolled in MA gradually increased. Between 2018 and 2020, the share of dialysis beneficiaries in MA rose from about 23 percent to 27 percent, while the share of dialysis beneficiaries in FFS Medicare fell from about 77 percent to 73 percent (Figure 5-2; FFS data not shown).

Beginning in 2021, the 21st Century Cures Act permits dialysis beneficiaries to enroll in MA plans. As a result of this statutory change, enrollment of dialysis beneficiaries in MA plans increased between December 2020 and January 2021 from 27 percent to 36 percent (Figure 5-2). By December 2022, the share of dialysis beneficiaries enrolled in MA plans was 47 percent.

The increase in MA enrollment by beneficiaries on dialysis since January 2021 is likely linked to the same factors that have increased MA's popularity among non-ESRD beneficiaries, including the availability of extra benefits (e.g., dental, hearing, and vision services) and lower cost-sharing liability. Given the magnitude of total health care expenses incurred by dialysis beneficiaries annually (for dialysis and other outpatient and inpatient services—averaging nearly $99,000 in 2021, with beneficiary out-of-pocket expenses averaging $13,400), these beneficiaries face significant out-of-pocket expense. Thus, they might enroll in an MA plan because such plans generally offer reduced cost sharing and are required to offer a maximum out-of-pocket (MOOP) limit on annual spending.[21] The mandatory MOOP limit was $8,300 for in-network services in 2023 (and $12,450 for in- and out-of-network services covered by preferred provider organizations (PPOs)), but most plans can elect to offer a lower MOOP limit. In 2023, the average MOOP was $4,835 for in-network services (and $8,659 for in- and out-of-network services covered by PPOs) (Ochieng et al. 2023). Beneficiaries who have full Medicaid coverage (about 39 percent of Medicare beneficiaries with ESRD compared with 13 percent of other Medicare beneficiaries) have their cost sharing covered by Medicaid but may still enroll in an MA plan for the extra benefits offered.

In addition, some dialysis organizations, including both large dialysis organizations (LDOs) and a midsize dialysis organization (U.S. Renal Care), offer online educational and informational resources about Medicare coverage options under MA. For example, each LDO has partnered with companies (SelectQuote and Chapter) that aim to help ESRD beneficiaries explore their insurance options, including comparing options across MA plans. Each LDO provides online links to these companies on their website. The extent to which new and existing beneficiaries on dialysis are using such services is unknown.

Beneficiaries preferring FFS Medicare may seek to limit cost-sharing liability by purchasing a Medigap policy; however, beneficiaries with ESRD, particularly those under age 65, may face difficulties obtaining Medigap insurance. FFS dialysis beneficiaries are less likely to purchase a Medigap plan than all other FFS beneficiaries (20 percent vs. 40 percent in 2021) because of:

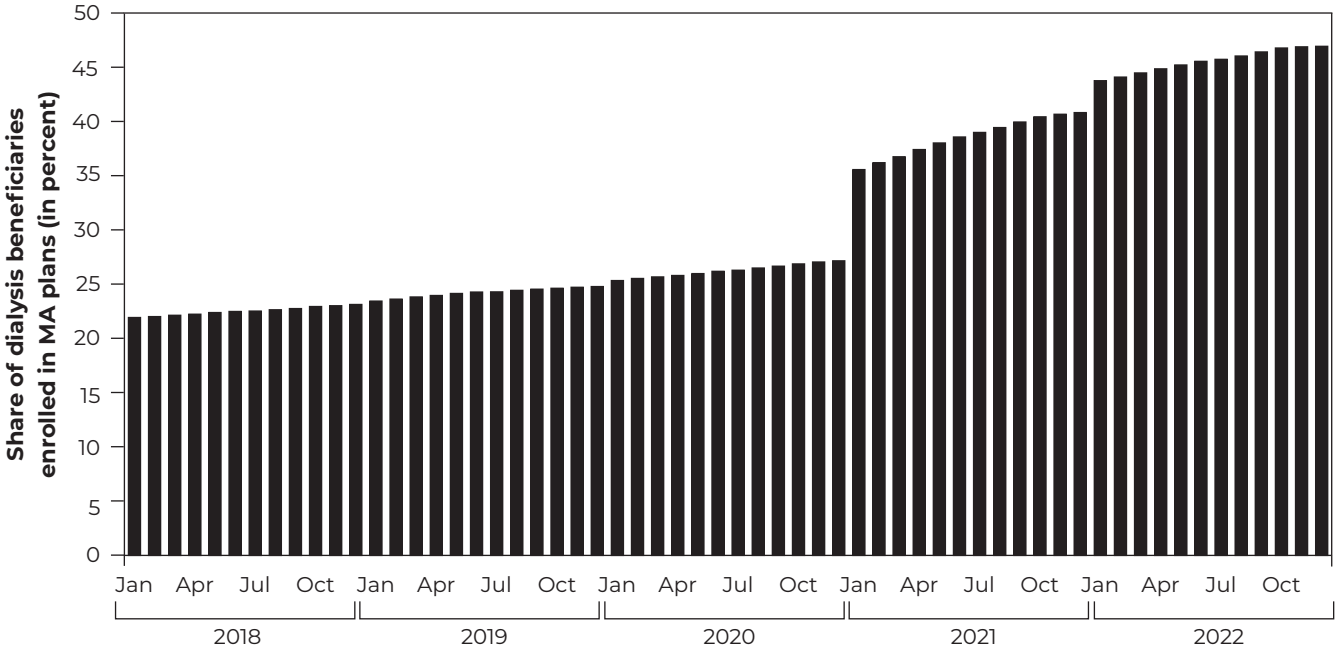
- Constraints in federal guaranteed-issue rights in obtaining these supplemental plans. Medicare beneficiaries have guaranteed-issue rights for Medigap plans—meaning that a plan must be offered regardless of their age, sex, or health status—when they turn 65. However, about half of individuals with ESRD become eligible for Medicare before reaching age 65, and federal guaranteed-issue rights do not extend to those beneficiaries at the time of their initial enrollment in Medicare.[22]

(continued next page)

Since 2021, the share of beneficiaries on dialysis enrolling in Medicare Advantage plans has accelerated (cont.)

FIGURE 5–2

The share of beneficiaries on dialysis enrolling in MA plans continued to increase between 2021 and 2022



Note: MA (Medicare Advantage). Beginning in 2021, the 21st Century Cures Act permits dialysis beneficiaries to enroll in MA plans.

Source: Data compiled by MedPAC from CMS enrollment data.

- The affordability of a Medigap plan. Even though beneficiaries with ESRD who are under 65 must be offered at least one Medigap plan in 35 states, the insurer can charge a higher premium based on age, sex, or existing health conditions, depending on state insurance rating rules.[23]

In addition to conventional MA plans, dialysis beneficiaries residing in selected geographic areas have access to ESRD special needs plans (SNPs) (specifically, C–SNPs, a type of SNP for individuals with chronic conditions). As of November 2023, few dialysis beneficiaries—about 4,400—were enrolled in 14 ESRD SNPs in 9 states (Arizona, California, Connecticut, Georgia, Kentucky, Michigan, New Jersey, Texas, and Virginia). ■

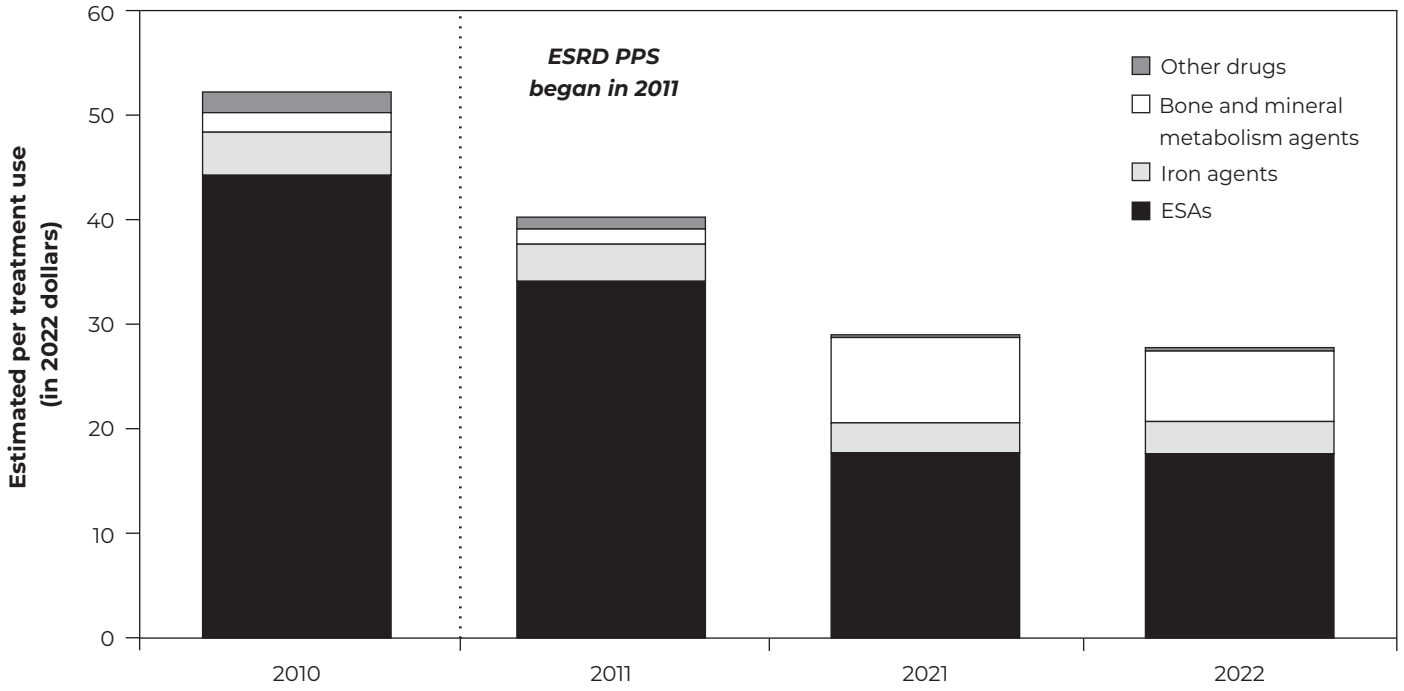
Quality under the ESRD PPS

Analysis of the most recent five-year period for which we have available claims and enrollment data for FFS dialysis beneficiaries found the following:

- In 2020, as the coronavirus pandemic took hold, mortality averaged 1.9 percent per month, up from an average of 1.6 percent in 2018 and 2019. The rate of mortality per month remained elevated in 2021 and 2022, averaging 2.0 percent.[24]

FIGURE 5–3

Use of ESRD drugs paid under the ESRD PPS has declined



Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent). To estimate drug use by therapeutic class, we hold the price of each drug constant and multiply drug units reported on claims in a given year by 2022 average sales price (ASP) plus 0 percent (or CMS's outlier limit if ASP data are not available). ESAs include epoetin alfa, epoetin beta, and darbepoetin. Iron agents include iron sucrose, sodium ferric gluconate, ferumoxytol, and ferric carboxymaltose. Bone and mineral metabolism agents include the vitamin D agents calcitriol, doxercalciferol, and paricalcitol and the calcimimetics cinacalcet and etelcalcetide. Other drugs include daptomycin, vancomycin, alteplase, and levocarnitine. Before the ESRD PPS was implemented, Medicare paid dialysis facilities separately for vitamin D agents and drugs in the ESA, iron, and other groups; since 2011, these products have been included in the ESRD PPS bundle and paid under the base payment rate. Prior to 2018, Medicare covered the available calcimimetic under Part D. Beginning in 2018, Medicare began to pay for all calcimimetics under the ESRD PPS. Per statutory and regulatory provisions, the ESRD PPS paid for calcimimetics (1) using a transitional drug add-on payment policy in 2018, 2019, and 2020, and (2) under the base rate as of 2021.

Source: MedPAC analysis of 100 percent claims submitted by dialysis facilities to CMS.

- Between 2018 and 2022, the share of FFS dialysis beneficiaries admitted to a short-stay hospital (beneficiaries with at least one admission in a given month) ranged from 12 percent per month to 14 percent per month. During the same period, 30-day readmission rates on an annual basis remained relatively steady at 21 percent of admissions.
- In 2020, 2021, and 2022, the share of FFS dialysis beneficiaries who used the ED on an outpatient basis (beneficiaries with at least one ED visit in a given month) averaged 10 percent per month, down from an average of 12 percent per month in 2018 and 2019.

Beneficiaries' fluid management is related to factors such as the adequacy of the dialysis procedure, defined as having enough waste removed from their blood. According to the Commission's analysis, between 2018 and 2022, between 97 percent and 98 percent of hemodialysis beneficiaries and between 92 percent and 93 percent of PD beneficiaries received adequate dialysis.

We assess the quality of anemia management by examining changes over time in (1) beneficiaries' hemoglobin level, as assessed by a blood test that measures the level of hemoglobin, the protein that

TABLE 5–3

Under the ESRD PPS, use per treatment of ESRD drugs has declined

	Mean units per treatment*			Aggregate percent change	
Dialysis drug	**2010**	**2021**	**2022**	**2010–2022**	**2021–2022**
ESAs					
Epoetin alfa (reference biologic)	5,214	1,051	1,031	–80%	–2%
Darbepoetin alfa	1.26	0.9	0.9	–31	1
Epoetin beta	N/A	4.2	4.3	N/A	4
Epoetin alfa (biosimilar)	N/A	111	84	N/A	–24
Iron agents					
Sodium ferric gluconate	0.15	0.05	0.05	–65	8
Iron sucrose	16.0	13.7	14.8	–7	8
Bone and mineral metabolism agents					
Paricalcitol	2.3	0.2	0.2	–93	–3
Doxercalciferol	0.9	1.2	0.8	–11	–38
Calcitriol	0.13	0.01	0.01	–91	7
Cinacalcet	N/A	49.4	38.3	N/A	–22
Etelcalcetide	N/A	2.0	1.7	N/A	–11
Antibiotics					
Daptomycin	0.22	0.08	0.10	–53	30
Vancomycin	0.02	0.01	0.01	–53	24
Other drugs					
Levocarnitine	0.010	0.001	0.002	–76	232
Alteplase	0.020	0.003	0.003	–86	9

Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not applicable [because drug not available in the U.S.]). 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.

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

carries oxygen in red blood cells, and (2) frequency of red blood cell transfusions.[25] Lower hemoglobin levels (which suggest underuse of ESAs and iron agents) can increase the frequency of red blood cell transfusions, while higher hemoglobin levels (greater than 12 g/dL) among patients maintained on higher doses of ESAs can increase their risk of death and cardiovascular events (congestive heart failure, myocardial infarction, and stroke). We found that, between 2018 and 2022, median hemoglobin levels have remained constant, averaging 10.5 g/dL. During this period, the share of FFS dialysis beneficiaries with lower hemoglobin levels (less than 10 g/dL) rose from 29 percent of beneficiaries to 31 percent of beneficiaries, while the share of FFS beneficiaries with levels between 10g/dL and 12g/dL fell from 66 percent to 63 percent. During this period, the share of beneficiaries with higher hemoglobin levels (exceeding 12 g/dL) ranged from 5 percent to 6 percent of FFS beneficiaries on dialysis.

We see fluctuation in rates of blood transfusion. Between 2018 and 2020, the proportion of FFS dialysis

TABLE 5–4 **Between 2021 and 2022, the number of kidney transplants increased**

	2018	2021	2022
Total transplants	21,167	24,670	25,500
Share of transplants from live donors	30%	24%	23%
Share receiving a transplant			
White	46	42	41
Black	26	29	29
Hispanic	19	20	20
Asian	7	7	8
Other	2	2	2

Note: Components may not sum to 100 percent due to rounding. Individuals receiving a kidney transplant include individuals with ESRD on dialysis (which replaces the filtering function of the kidneys when they fail) and individuals who receive a kidney transplant before their kidney function deteriorates to the point of needing dialysis.

Source: Organ Procurement and Transplantation Network.

beneficiaries receiving a blood transfusion declined from an average of 2.5 percent per month to 2.4 percent per month. In 2021 and 2022, the share of FFS dialysis beneficiaries receiving a blood transfusion increased to an average of 2.7 percent per month.

Access to home dialysis

Researchers have shown that the ESRD PPS is associated with an overall increase in the use of home dialysis (Lin et al. 2017). Between 2018 and 2022, the share of beneficiaries dialyzing at home steadily increased from 11 percent per month to nearly 16 percent per month. While we are encouraged by this increase, differences by race persist: Black beneficiaries are less likely to use home methods. Although about 31 percent of Medicare FFS beneficiaries with ESRD are Black, only 24 percent of beneficiaries who dialyze at home are Black. Between 2018 and 2022, the proportion of beneficiaries undergoing home dialysis training was relatively small but increased slightly, ranging from a monthly average of 0.7 percent to 0.9 percent of FFS beneficiaries on dialysis.

Researchers have identified many factors that affect the use of home dialysis, both clinical (e.g., patients' other health problems and prior nephrology care) and nonclinical (e.g., patients' social circumstances and knowledge about treatment options as well as physicians' training and preference). For example, nephrology trainees reported low and moderate levels of preparedness for managing patients on home hemodialysis and PD, respectively (Gupta et al. 2021). Some beneficiaries report that they were never informed about their dialysis modality options. Facility factors, such as unused in-center capacity or additional in-center shifts and dialysis facility staff experience, can also affect use of home dialysis (Walker et al. 2010). During the coronavirus pandemic, however, both LDOs and midsize providers reported that their patients showed increased awareness of and interest in home dialysis.[26]

Some clinical and nonclinical factors affecting home dialysis use are amenable to intervention. For example, between 2008 and 2018, under an integrated care delivery system (Kaiser Permanente Northern California), PD use among new dialysis patients more than doubled, from 15 percent to 34 percent. To augment the use of home dialysis, the health care system implemented a multidisciplinary, system-wide

approach that increased patient and family education, educated health care professionals about the importance of PD, adopted operational improvements, monitored outcomes, and shared best practices with staff (Pravoverov et al. 2019).

Access to kidney transplantation

Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical outcomes and quality of life. In addition, transplantation results in lower Medicare spending. In 2021, average Medicare spending for patients on dialysis (nearly $98,000) was more than twice the annual spending of those who had a functioning kidney transplant (nearly $44,000 in 2021) (United States Renal Data System 2023). However, demand for kidney transplantation exceeds the supply of available kidneys. Besides donation rates, factors that affect access to kidney transplantation include the clinical allocation process; patients' health literacy, clinical characteristics, and preferences; the availability of education for patients; clinician referral for transplant evaluation at a transplant center; communication between the dialysis facility and the transplant center; and transplant center policies.

Between 2018 and 2022, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 5 percent per year, to 25,500 (Table 5-4).[27] The increase was mostly due to an increase in the number of deceased donor transplants. During this period, the share of transplants for Asian, Black, and Hispanic patients rose modestly (Table 5-4). According to researchers, a kidney allocation system implemented in 2014 by the United Network for Organ Sharing led to a narrowing of the disparities in national kidney transplant rates among White, Black, and Hispanic patients on the transplant waiting list (Melanson et al. 2017).

Providers' access to capital: Growth trends indicate that access is adequate

Dialysis providers need access to capital to maintain and modernize their facilities and to improve patient care delivery. In general, current growth trends among dialysis providers indicate that the dialysis industry is attractive to for-profit facilities and investors, with the two LDOs and other renal companies appearing to have adequate access to capital. For example:

- In 2022, Fresenius Medical Care completed a three-way merger that includes Fresenius Health Partners (its value-based care division), Interwell Health, and Cricket Health. The new company, which will operate under the Interwell Health brand, will focus on services for individuals with earlier stages of kidney disease and anticipates managing the care of roughly 300,000 individuals in the U.S. with kidney disease, with more than $11 billion in costs under management by 2025 (Landi 2022).
- In 2023, DaVita launched a kidney care–focused medical device company with Medtronic that specializes in developing novel kidney care products and solutions, including home-based products to make different dialysis treatments more accessible (DaVita 2023a).
- In 2023, DaVita Venture Group (an ancillary service of DaVita) continued to fund select venture capital investments in early-stage companies, including (1) acquiring a transplant software company to create greater connectivity among transplant candidates, transplant centers, physicians, and care teams; (2) investing in a company that offers advance care planning and virtual palliative care; and (3) investing in a new pharmaceutical company to bring ESRD drugs to market (DaVita 2023a).

Another indicator of the industry's relatively good access to capital is that, during the past decade, several companies—both small and large—have entered the renal care field to improve treatment of individuals with CKD and ESRD, including Outset Medical (in 2010), Cricket Health (in 2015), Somatus (in 2016), and CVS (in 2018). Most recently, in 2022, Satellite Healthcare Inc., a nonprofit, midsize outpatient dialysis chain, and Dialyze Direct, a provider of home hemodialysis services in skilled nursing facilities (SNFs), announced their letter of intent to collaborate on opportunities such as offering home hemodialysis and CKD management to patients in SNFs (Satellite Healthcare 2022). Another recent investment highlighting good access to capital involves MA plans that are expanding kidney care. Gold Kidney Health Plan, which offers MA special needs plans developed by nephrologists,

announced that the company received $60 million from a health care investment group (Chicago Pacific Founders) to increase its ability to offer MA plan choices to patients with kidney disease (Gold Kidney Health Plan 2022).

In public financial filings, the two LDOs reported generally positive financial performance related to their dialysis business for 2023, including improvements in productivity and earnings growth (DaVita 2023b, Fresenius Medical Care 2023b). Since 2010, these organizations have grown through large acquisitions of and mergers with other dialysis facilities and other health care organizations. For example, during this period, both LDOs acquired midsize for-profit organizations: DaVita acquired Purity and Renal Ventures and Fresenius Medical Care acquired Liberty Dialysis. The LDOs have entered into value- and risk-based programs with private payers to provide care to commercial and MA ESRD and CKD patients. Under these arrangements, the companies' financial performance is based on their ability to manage a defined scope of medical costs within certain parameters for clinical outcomes (Fresenius Medical Care 2022). Both LDOs are participants in CMMI's current Kidney Care Choices Model.

The two LDOs, in addition to operating three-quarters of all dialysis facilities, are each vertically integrated (DaVita 2023a, Fresenius Medical Care 2023a). For example, other health care services that one or both LDOs operate include an ESRD-related laboratory, a pharmacy, and centers that provide vascular access services; they both provide ESRD-related care coordination and disease management services to government and nongovernment payers (including MA plans); and they operate dialysis facilities internationally. One LDO manufactures, acquires, in-licenses, and distributes ESRD-related pharmaceutical products (e.g., phosphate binders and iron replacement products) and manufactures dialysis products (hemodialysis machines, peritoneal cyclers, dialyzers, peritoneal solutions, hemodialysis concentrates, bloodlines, and systems for water treatment) and nondialysis products, including acute cardiopulmonary and apheresis products. This LDO supplies dialysis facilities that it owns, operates, or manages with dialysis products, and it sells dialysis products to other dialysis service providers.

Another positive indicator of the dialysis sector's strong access to capital is its all-payer margin. Using cost report data submitted by freestanding dialysis facilities to CMS, we found that the 2022 all-payer margin was roughly 14 percent. The all-payer margin is affected by the revenues that providers derive from furnishing care to patients with all sources of coverage, including FFS Medicare, MA, other government payers, and commercial payers, as well as to patients with acute kidney injury.[28] Although commercial payment rates vary, average rates established under commercial contracts are generally significantly higher than Medicare rates. According to one LDO, patients with commercial coverage (including hospital dialysis services) account for 10 percent of its treatments and about 32 percent of its U.S. dialysis patient revenues, while patients with government coverage account for 90 percent of its treatments and 68 percent of its U.S. dialysis patient revenues (DaVita 2019). The Commission found that, accounting for age and wage index differences (geographic location), in 2018, the prices MA plans paid for dialysis services were on average about 14 percent higher than FFS Medicare rates (Medicare Payment Advisory Commission 2021). Researchers estimated commercial and Medicare revenue per treatment for dialysis services in 2017 and found that commercial revenue per treatment was nearly four times greater than Medicare revenue per treatment (Childers et al. 2019). The increase in FFS labor and capital costs and decrease in total treatment volume experienced in 2022 may also have been a factor in the decline of the all-payer margin, which was lower in 2022 than in 2021 (14 percent and 17 percent, respectively).

Medicare payment and providers' costs: Increased costs in most cost categories contributed to decline in FFS Medicare margins

Between 2021 and 2022, total FFS spending for outpatient dialysis services dropped by 12 percent, due predominantly to a sharp decline in the number of FFS dialysis beneficiaries, as dialysis beneficiaries' enrollment in MA plans soared. Medicare's payment per FFS dialysis treatment increased 2 percent while total cost per treatment rose by nearly 6 percent in 2022. In 2022, the aggregate FFS Medicare margin decreased to –1.1 percent.

Medicare payments for outpatient dialysis services

In 2022, FFS per capita annual spending for outpatient dialysis services remained steady relative to the previous year, increasing by 0.5 percent to roughly $30,300. Total FFS Medicare spending for these services, however, declined 12 percent from 2021, to $8.8 billion. The decline is predominantly due to MA plans' increasing enrollment of dialysis beneficiaries beginning in 2021. Specifically, between 2021 and 2022, the total number of FFS beneficiaries on dialysis and FFS treatments declined by 13 percent and 14 percent, respectively. A statutory update (of 1.9 percent) increased the base ESRD PPS payment rate in 2022.

Between 2020 and 2021, Part D spending for ESRD oral-only phosphate binders declined for FFS dialysis beneficiaries

Phosphate binders, currently covered under Part D, will be the last oral-only drug group to be included in the ESRD PPS bundle in 2025 (the inclusion of oral-only drugs in the ESRD PPS bundle has been delayed by statute); therefore, we track Part D spending for this group. Between 2020 and 2021 (the most recent year for which data are available), spending for phosphate binders furnished to dialysis FFS beneficiaries declined by 16 percent to $0.8 billion.[29] The decline in total spending for phosphate binders for FFS dialysis beneficiaries is linked to the substantial increase in dialysis beneficiaries enrolling in MA in 2021. Among FFS beneficiaries on dialysis who used phosphate binders, per capita spending in 2021 and 2022 remained flat at about $4,300 per patient. Similar shares (roughly 70 percent) of FFS dialysis beneficiaries with Part D coverage were prescribed phosphate binders in 2020 and 2021, and Part D spending for phosphate binders accounted for a similar share of their Part D spending in each year (ranging from 34 percent to 36 percent). Medicare spending for ESRD drugs under Part D is not included in the Commission's analysis of dialysis facilities' financial performance under the ESRD PPS.

As of January 1, 2025, the Secretary will have the authority to include phosphate binders—currently covered under Part D—in the ESRD PPS bundled payment.[30] Their inclusion is intended to better manage 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. Including phosphate binders in the ESRD PPS bundle might also improve provider efficiency.

Providers' costs for outpatient dialysis services under the ESRD PPS

To assess the appropriateness of costs for dialysis services paid for under the ESRD PPS, we examine whether aggregate dialysis facility costs reflect costs that providers would incur in furnishing high-quality care. For this analysis, we used 2021 and 2022 cost reports and claims submitted to CMS by freestanding dialysis facilities. For those years, we looked at the growth in the cost per treatment and how the total volume of treatment affected that cost.

Cost growth under the PPS Between 2021 and 2022, total cost per treatment rose by nearly 6 percent, from $270 per treatment to nearly $286 per treatment. Though ESA and supply costs declined by 3 percent and 1 percent, respectively, costs rose sharply for:

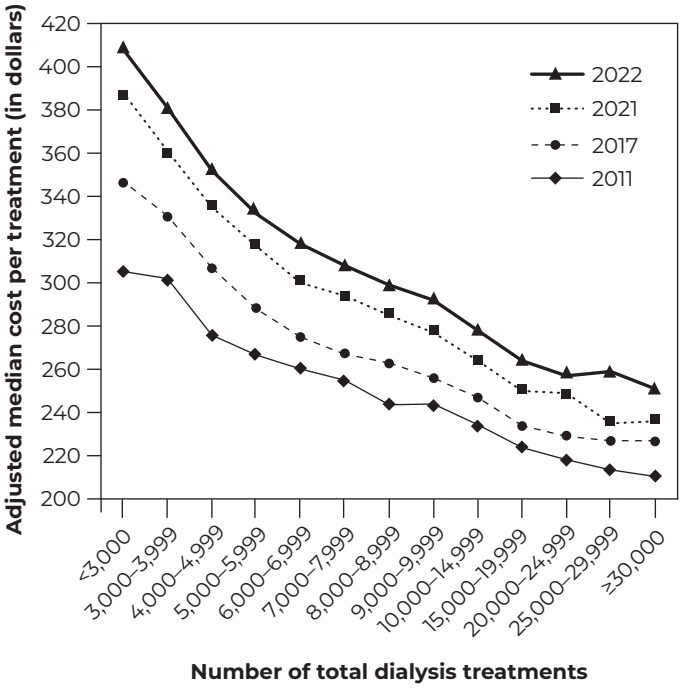
- capital, labor, and administrative and general expenses, which each rose by 7 percent and accounted for 19 percent, 34 percent, and 27 percent of the cost per treatment, respectively, in 2022; and
- ESRD drugs (other than ESAs), which rose by 9 percent and accounted for 3 percent of cost per treatment in 2022, and labs, which rose by 10 percent and accounted for 1 percent of providers' cost per treatment in 2022.

Historically, dialysis facilities have experienced lower cost growth than they did between 2021 and 2022. For example, between 2018 and 2021, total cost per treatment increased by 0.4 percent per year, with labor and capital cost per treatment rising by 3 percent and 4 percent per year, respectively. Likewise, cost growth was low between 2014 and 2017: Total cost per treatment increased by 0.6 percent per year, with labor and capital cost per treatment each increasing by 3 percent per year.

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 2021 and 2022, per treatment costs fell by 0.5 percent for facilities in the 25th percentile

FIGURE 5–4

Higher-volume freestanding dialysis facilities had lower cost per treatment, 2011–2022



Note: Cost per treatment is adjusted to remove differences in the cost of labor.

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

of cost growth, compared with a rise of 11 percent for facilities in the 75th percentile. The growth in cost per treatment is related to facility size. Between 2021 and 2022, the growth in the total cost per treatment was higher for the smallest facilities (e.g., facilities furnishing fewer than 4,000 treatments had cost growth averaging 8 percent) compared with all other facilities (with cost growth averaging nearly 6 percent).

The extent to which some of the variation in costs among facilities results from differences in the accuracy of facilities' reported data is unknown. Our analysis of cost report data shows substantial variation in selected categories as reported by the five largest dialysis organizations. For example, in 2022, labor cost varied by $49 per treatment, and capital costs varied by $42 per treatment. The Commission estimated, based on findings from CMS's audit of facility cost reports, that unallowable costs reported by dialysis facilities could have amounted to about 4 percent of total reported costs in 2018 (Medicare Payment Advisory Commission 2022). If 4 percent of reported costs are unallowable, the estimated aggregate FFS Medicare margin would be understated by nearly 4 percentage points.

Cost per treatment is correlated with facility service volume To examine the relationship between a facility's cost per treatment and the total number of treatments a facility furnishes, we adjusted the cost per treatment to remove differences in the cost of labor across geographic areas and included all treatments regardless of payer. Our analysis showed, in each year from 2011 through 2022, a statistically significant relationship between the total number of treatments and cost per treatment (correlation coefficient equaled −0.5) (Figure 5-4). That is, the greater the facility's service volume, the lower its costs per treatment. In each year, facilities that qualified for increased Medicare payment due to low volume had substantially higher cost per treatment for capital as well as administrative and general services compared with all other facilities.

The trend in the aggregate FFS Medicare margin for freestanding dialysis facilities

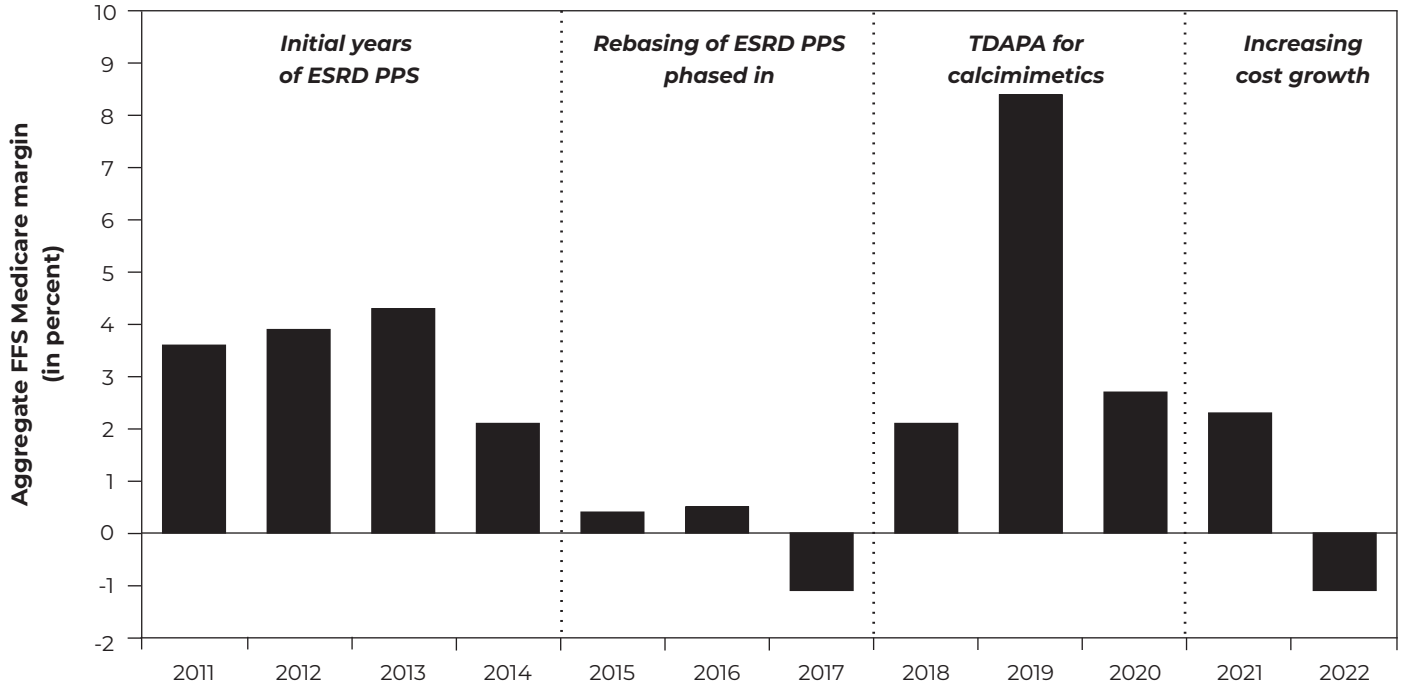
The Commission assesses current payments and costs for FFS dialysis services for freestanding dialysis facilities by comparing Medicare's payments with facilities' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2022.

The aggregate average FFS Medicare margin reached 8.4 percent in 2019 (the highest since the ESRD PPS was implemented in 2011) but has since declined, falling to 2.7 percent in 2020 and 2.3 percent in 2021. Dialysis facilities' FFS Medicare margin fell further in 2022, to −1.1 percent.

Dialysis facilities' financial performance under the ESRD PPS has been variable due to statutory and regulatory changes as well as the use and profitability of certain ESRD-related drugs (Figure 5-5). During the initial years of the ESRD PPS, the aggregate FFS Medicare margin increased as providers furnished fewer ESRD drugs per treatment. Between 2014 and 2017, facilities' financial performance under FFS

FIGURE 5–5

Aggregate FFS Medicare margin declined in 2022 due to increasing cost growth



Note: ESRD (end-stage renal disease), PPS (prospective payment system), TDAPA (transitional drug add-on payment adjustment). Pandemic-related federal relief funds are not included in the data presented in this figure.

Source: Compiled by MedPAC from cost reports and claims submitted by facilities to CMS.

Medicare reversed, and the aggregate FFS Medicare margin declined from 2.1 percent to –1.1 percent because of statutorily required payment adjustments to account for the decline in ESRD drug use under the ESRD PPS. Provisions in the statute required CMS to rebase the payment rate in 2014 (reducing the payment rate by about 3.4 percent) and limit payment updates from 2015 through 2018.

In 2018 and 2019, however, the aggregate FFS Medicare margin increased due to the profitability of the calcimimetics paid under the TDAPA policy—to 2.1 percent in 2018 and to 8.4 percent in 2019 (Figure 5-5).[31,32] In 2020, the aggregate FFS Medicare margin decreased to 2.7 percent (3.7 percent when including FFS Medicare's share of pandemic relief funds) because cost per treatment increased and the TDAPA payment declined from average sales price (ASP) plus 6 to ASP plus 0. In 2021, the aggregate FFS Medicare margin declined again to 2.3 percent, due to increasing cost per treatment for all cost categories (except ESRD drug costs).

The aggregate FFS Medicare margin further declined to –1.1 percent in 2022, partly attributable to growth in labor and capital costs, which both increased by 7 percent between 2021 and 2022, well above the historical average. Both LDOs reported a challenging labor market in 2022, and the high growth in labor costs in 2022 may be linked to staff shortages, high turnover rates, higher-than-normal merit increases, higher incentive compensation, increased utilization of contract labor, and lower productivity due to higher training costs (DaVita 2022b, Fresenius Medical Care

TABLE 5–5

In 2022, the aggregate FFS Medicare margin of freestanding dialysis facilities varied by treatment volume

Provider type	Aggregate FFS Medicare margin	Share of freestanding dialysis facilities	Share of freestanding dialysis facility treatments
All	–1.1%	100%	100%
Urban	–0.4	84	88
Rural	–4.5	16	12
Treatment volume (quintile)			
Lowest	–24.1	20	7
Second	–13.4	20	13
Third	–5.0	20	18
Fourth	1.6	20	24
Highest	7.4	20	39

Note: FFS (fee-for-service). Components may not sum to 100 percent due to rounding.

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

2022). In addition, total treatment volume declined between 2021 and 2022, with a material (negative) impact on this sector's FFS Medicare margin (and all-payer margin). Each LDO experienced a 2 percent decline in total treatment volume between 2021 and 2022. Unlike in previous years, add-on payments (for the drug Korsuva and for the Tablo Hemodialysis System) did not have a material effect on dialysis facilities' FFS Medicare margin because of the low use of these services.

The aggregate FFS Medicare margin varies by treatment volume

Aggregate FFS Medicare margins in 2022 decidedly varied by treatment volume: Facilities in the lowest volume quintile had margins below –20 percent, while facilities in the top volume quintile had margins of over 7 percent (Table 5-5). Urban facilities averaged higher margins than rural facilities (–0.4 percent vs. –4.5 percent). Total treatment volume accounted for much of the difference in margins between urban and rural facilities: Urban dialysis facilities are larger on average in terms of the number of treatment stations and total treatments provided. For example, in 2022, urban facilities averaged roughly 10,700 treatments, while rural facilities averaged about 7,500 treatments (data not shown). Higher-volume facilities had lower cost per treatment (Figure 5-4, p. 150).

Although some rural facilities have benefited from the ESRD PPS's 23.9 percent low-volume adjustment and 0.8 percent rural adjustment, the Commission has found that neither adjustment appropriately targets low-volume, geographically isolated facilities that are critical to beneficiary access (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014). The Commission's recommendation to replace the current low-volume payment adjustment and rural adjustment with a single low-volume and isolated adjustment, where low-volume criteria are empirically derived, would better protect isolated low-volume rural facilities that are necessary for beneficiary access (Medicare Payment Advisory Commission 2020).

Projecting the aggregate FFS Medicare margin for 2024

We project that the aggregate FFS Medicare margin will slightly increase in 2024, to 0 percent. To estimate 2024

margins using 2022 data, the Commission considers providers' historical cost growth and policy changes affecting payments effective in 2023 and 2024. These factors include:

- statutory updates to the dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) of 3.0 percent in 2023 and 2.1 percent in 2024;
- reductions in payments of 0.16 percent in 2023 and 2024 due to the ESRD Quality Incentive Program; and
- reductions in payments in 2023 and 2024 due to the ETC Model (CMMI's mandatory model), which CMS estimates will total $2 million in 2023 and $10 million in 2024.

Factors not considered in this projection that might have a positive effect on providers' financial performance include:

- add-on payments in 2023 for a new ESRD drug that treats anemia, which could affect providers' financial performance; and
- both LDOs' increasing treatment volumes and productivity efficiencies in 2023.

How should FFS Medicare payments change in 2025?

Most payment adequacy indicators—beneficiary access to care, quality of care, provider access to capital—for outpatient dialysis facilities are adequate, though the projected FFS Medicare margin for 2024 is low. Still, dialysis facilities continue to become more efficient under the ESRD PPS, as measured by declining use of most injectable dialysis drugs with little to no measurable impact on beneficiaries' health outcomes. Facilities have additional incentives to maximize the efficiency of their in-center capacity utilization: Demand for home dialysis has increased, and ESRD incidence has slowed over the past decade.

We note that, since 2020, in addition to the base payment rate, Medicare includes a TDAPA under the ESRD PPS that pays dialysis facilities for certain new drugs and biologics based on the product's ASP for a two-year period. The new anemia drug paid under a TDAPA beginning in August 2023 may increase FFS Medicare payments relative to facilities' costs. Specifically, CMS does not reconcile the cost and utilization of the new drug (which is paid under a TDAPA) within an existing functional category (e.g., anemia category) with the cost and utilization of the drugs already included in the functional categories that are paid under the ESRD PPS payment bundle.

Under current law, Medicare's base payment rate under the ESRD PPS will be increased in 2025 based on the forecasted increase in the ESRD market basket less a forecasted increase in productivity. The final update for 2025 will not be set until summer 2024, but CMS currently forecasts a 1.8 percent increase in the base payment rate. The final 2025 update will include newer forecasts of growth in input prices and productivity and thus could be lower or higher than the current projected update.

In addition, in 2025, CMS will have statutory authority to pay for phosphate binders under the ESRD PPS. Currently, phosphate binders are paid under Part D. Covering such products under the ESRD PPS may have a positive effect on providers' financial performance. Three of the five largest dialysis organizations operate their own pharmacies (Government Accountability Office 2023). According to these organizations, operating their own pharmacies offers advantages such as managing costs and maintaining greater control of and more complete information on their patients' prescriptions (Government Accountability Office 2023). Moreover, one dialysis organization established a company (Vifor Fresenius Medical Care Renal Pharma) that, since 2014, markets a phosphate binder (Velphoro) as well as other renal dialysis drugs prescribed to dialysis patients. In 2021, Part D spending for Velphoro by FFS dialysis beneficiaries was $260 million.

RECOMMENDATION 5

For calendar year 2025, the Congress should update the 2024 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

RATIONALE 5

Our indicators of payment adequacy are generally positive, including beneficiaries' access to care, the

supply and capacity of providers, volume of services, and access to capital. Providers have become more efficient in the use of dialysis drugs under the ESRD PPS. Indicators of quality of care have generally remained stable. The aggregate FFS Medicare margin was –1.1 percent in 2022 and is projected to be 0 percent in 2024. We are uncertain about the effects of the add-on payments for new renal dialysis drugs in 2023 and 2024, but our prior analysis showed that add-on payments for calcimimetics between 2018 and 2020 contributed to a substantial increase in provider profitability during that period. The two LDOs, both of which are publicly traded companies, recently made optimistic statements about their dialysis business; for example, each reported increasing treatment volume and decreasing mortality, and both achieved productivity gains in 2023 (DaVita 2023c, Fresenius Medical Care 2023b).

FFS Medicare margins tend to be lower in low-volume and in rural dialysis facilities, in spite of the payment system's low-volume and rural adjustments, which increase payments by 23.9 percent and 0.8 percent, respectively. Previous Commission analyses have found that neither adjustment appropriately targets low-volume, geographically isolated facilities. The Commission has held that payments to rural providers should target facilities that are critical for beneficiary access (that is, facilities that are both low volume and isolated). Further, the magnitude of rural payment adjustments should be empirically derived, and the adjustments should encourage provider efficiency. In June 2020, the Commission recommended that the Secretary replace the current low-volume and rural payment adjustments with a single payment adjustment that considers both a facility's distance to the nearest facility and its treatment volume, thereby directing extra payments to the low-volume and isolated facilities that are most necessary to ensure beneficiary access to care (Medicare Payment Advisory Commission 2020).

IMPLICATIONS 5

Spending

- This recommendation would have no effect on federal program spending relative to the statutory update.

Beneficiary and provider

- We expect beneficiaries to continue to have good access to outpatient dialysis care. We do not anticipate any negative effects on beneficiary access to care. This recommendation is expected to have a minimal effect on providers' willingness and ability to care for Medicare beneficiaries. ■

Endnotes

1 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to all individuals (across all types of health coverage) who have ESRD.

2 Throughout this chapter, we use the term *FFS Medicare* as equivalent to the CMS term *original Medicare*.

3 In this chapter, the term *drugs* refers to both drugs and biologics. The term *biologics* refers to biological products.

4 Clinicians receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis–related management services (which include managing the dialysis prescription and prescribing ESRD drugs); payment varies based on the number of visits per month, the beneficiary's age (adult vs. pediatric beneficiaries under 20 years of age), and whether the beneficiary receives dialysis in a facility or at home.

5 Some have raised concerns that joint ventures between dialysis organizations and physicians create financial incentives for participating physicians that could inappropriately influence decisions about patient care (Berns et al. 2018). Under federal disclosure requirements, a dialysis facility must report certain ownership information to CMS and its state survey agency but is not required to disclose such information to its patients, researchers, or members of the public.

6 In 2011, CMS delayed including ESRD oral-only drugs (which, at the time, included calcimimetics and phosphate binders paid for under Part D) in the ESRD PPS bundle to give facilities additional time to make operational changes and logistical arrangements to furnish these products to their beneficiaries. Subsequently, Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 delayed including oral-only renal dialysis drugs in the ESRD PPS bundled payment until January 1, 2025. However, with the availability of an injectable calcimimetic in 2017, CMS no longer considered these drugs oral only. From 2018 through 2020, calcimimetics were paid for under the ESRD PPS using a transitional drug add-on payment adjustment; beginning in 2021, these drugs were included in the ESRD PPS's payment bundle.

7 For pediatric dialysis beneficiaries (age 17 years and under), the base rate is adjusted for age and type of dialysis.

8 New drugs ineligible for a separate add-on payment include generic drugs, which the Food and Drug Administration (FDA) approves under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, and drugs approved for a new dosage form (e.g., pill size, time-release forms, chewable or effervescent pills); drugs approved for a new formulation (e.g., new inactive ingredient); drugs approved that were previously marketed without a new drug application (NDA); and drugs approved that changed from prescription to over-the-counter availability. CMS will identify these drugs using the NDA classification code that the FDA assigns to a given drug.

9 During the TDAPA period, CMS pays for Korsuva and Jesduvroq using the average sales price. In 2024, CMS will begin a post-TDAPA policy that adds three years to the time that facilities receive add-on payments for new ESRD drugs in an existing ESRD functional drug category. The post-TDAPA will be case-mix adjusted, set at 65 percent of payments for the given dialysis drug, applied to all PPS payments, and paid for three years. Thus, both add-on payments (the TDAPA and post-TDAPA) provide increased payments for five years for new ESRD drugs in an existing functional category.

10 CMS sets the new item's payment rate at 65 percent of the price that the Medicare administrative contractors establish.

11 The Commission's *Payment Basics* series provides more information about Medicare's method of paying for outpatient dialysis services (see Outpatient Dialysis Services Payment System, available at https://www.medpac.gov/wp-content/uploads/2022/10/MedPAC_Payment_Basics_23_dialysis_FINAL_SEC.pdf).

12 This figure is based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.

13 Beginning in 2021, the ETC Model applies to certain dialysis facilities and managing clinicians who furnish monthly capitated payment services. CMS selected participants according to their location in randomly selected geographic areas (hospital referral regions), stratified by region, to account for approximately 30 percent of adult dialysis beneficiaries. CMS adjusts participants' payment upward or downward based on their home dialysis and kidney transplant rates. CMS estimated that the Medicare program would, on net, save $28 million over the ETC Model's six-year duration through decreased payments to dialysis facilities.

14 If we approximate marginal cost as total Medicare costs minus fixed building and equipment costs, then marginal profit can be calculated as follows: Marginal profit = (payments for Medicare services – (total Medicare costs –

fixed building and equipment costs)) / Medicare payments. This comparison is a lower bound on the marginal profit because we do not consider any potential labor costs that are fixed.

15 Some portion of the decline in 2021 in the number of FFS dialysis beneficiaries and treatments may also have been due to the ongoing effects of the coronavirus pandemic. According to one of the LDOs, the overall number of patients that the company treated in 2021 fell by about 0.5 percent from 2020, primarily due to an increase in mortality rates because of COVID-19. These rates were partially offset by patients starting dialysis (DaVita 2022a).

16 For example, researchers have reported that all-cause mortality among dialysis patients is significantly higher in winter compared with other seasons.

17 Medicare pays for up to three dialysis treatments per week, with exceptions made with medical justification (Centers for Medicare & Medicaid Services 2023).

18 These drug classes accounted for nearly all ESRD drug spending (about 97 percent) in 2010, the year before the new payment method was implemented.

19 To measure changes in the use of drugs in the payment bundle, we combine drugs within and across therapeutic classes by multiplying the number of drug units reported on claims in a given year by each drug's 2022 ASP, with one exception. Because 2022 ASP data were not available for cinacalcet, we used CMS's TDAPA payment limit for the fourth quarter of 2020. By holding the price constant, we account for the different billing units assigned to a given drug.

20 While this section focuses on changes in individual quality metrics, it is worth noting that Medicare has implemented numerous programs that aim to improve the quality of care for late-stage chronic kidney disease and ESRD. A discussion of these programs can be found in the Commission's March 2023 report to the Congress at https://www.medpac.gov/wp-content/uploads/2023/03/Ch6_Mar23_MedPAC_Report_To_Congress_SEC.pdf.

21 MA plans negotiate with medical providers and facilities that join their network (i.e., in-network providers) to determine the amount that the MA plan will pay the provider or facility for providing care to plan enrollees; the negotiated payment amount may differ from the amount paid under FFS Medicare. If a plan enrollee receives care from a provider or facility that is outside of the plan's network, the provider is paid the amount they would have received under FFS Medicare.

22 Once beneficiaries with ESRD turn 65, for a 6-month period that begins on the first day of the month in which they turn 65 (and are enrolled in Medicare Part B), they can purchase a Medigap plan without regard to their age, sex, or health status. Outside of the federal guaranteed-issue window, Medigap plans offered to beneficiaries with ESRD are limited; 35 states require insurers to offer at least one Medigap plan to beneficiaries under age 65, but only 30 states require insurers to offer a plan to those entitled to Medicare due to ESRD rather than because of disability (AARP 2022, American Kidney Fund 2022).

23 Some FFS dialysis beneficiaries get financial assistance from the American Kidney Fund, a nonprofit organization whose funding sources include dialysis providers and pharmaceutical manufacturers, via need-based grants to pay for health insurance premiums, prescription medications, and other items and services.

24 Mortality rates for adult patients on dialysis (adjusted for age, sex, race/ethnicity, primary cause of ESRD, and duration of ESRD) increases with age. In 2021, the adjusted mortality rate was 91 per 1,000 patient years (1,000 PYs) for individuals between the ages of 18 and 44, 150 per 1,000 PYs for individuals between the ages of 45 and 64, 232 per 1,000 PYs for individuals between the ages of 65 and 74, and 304 per 1,000 PYs for individuals 75 years and older (United States Renal Data System 2023).

25 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.

26 See our March 2020 report to the Congress for more information on the factors that affect use of home dialysis and the factors associated with some patients' discontinuation of home dialysis (available at http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch6_sec.pdf?sfvrsn=0).

27 Individuals receiving a kidney transplant include individuals with ESRD on dialysis (which replaces the filtering function of the kidneys when they fail) and individuals who receive a kidney transplant before their kidney function deteriorates to the point of needing dialysis.

28 Since 2017, dialysis facilities are able to furnish dialysis to beneficiaries with acute kidney injury (AKI), as mandated by the Trade Preferences Extension Act of 2015. AKI is the

sudden loss of kidney function, typically caused by an event that leads to kidney malfunction, such as dehydration, blood loss from major surgery or injury, or the use of medicines. In 2022, Medicare spending for outpatient dialysis services for FFS beneficiaries with AKI was nearly $73 million, a decline from nearly $80 million in 2021. Medicare pays facilities the ESRD PPS base rate adjusted by the PPS wage index for the treatment of beneficiaries with AKI. In addition, for beneficiaries with AKI, Medicare pays dialysis facilities separately for drugs, biologics, and laboratory services that are not renal dialysis services.

29 Between 2017 and 2019, the FDA approved generic versions of several types of phosphate binders (including lanthanum, sevelamer carbonate, and sevelamer hydrochloride).

30 Statutory changes (in the American Taxpayer Relief Act of 2012; the Protecting Access to Medicare Act of 2014; and the Stephen Beck, Jr., ABLE Act of 2014) delayed until January 1, 2025, the inclusion of oral-only ESRD drugs in the ESRD PPS bundled payment.

31 In 2019, there was an anomalous increase compared with prior years in non-ESRD-related drug costs for facilities associated with a dialysis organization.

32 The sharp increase in the aggregate FFS Medicare margin in 2019 was driven by the availability of generic versions of the oral calcimimetic in 2019. There is a two-quarter lag in the data used to set ASP-based payment rates under the TDAPA policy, which can result in a difference between the average provider acquisition cost for a drug and the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that change is reflected in the ASP data that Medicare uses to pay providers. When newly available generic drugs enter the market, their ASPs are often substantially lower than their brand counterparts, but payment amounts remain at the higher brand level for typically two quarters (or more).

References

AARP. 2022. Can I get Medigap insurance if I'm under 65? https://www.aarp.org/health/medicare-qa-tool/medigap-insurance-under-65/.

American Kidney Fund. 2022. Kidney failure patients under 65: Understanding the challenges for patients with Medicare. https://www.kidneyfund.org/sites/default/files/media/documents/2021-medigap-map-infographic.pdf.

Berns, J. S., A. Glickman, and M. S. McCoy. 2018. Dialysis-facility joint-venture ownership: Hidden conflicts of interest. *New England Journal of Medicine* 379, no. 14 (October 4): 1295–1297.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2023. *Medicare claims processing manual—Chapter 8: Outpatient ESRD hospital, independent facility, and physician/supplier claims.* Baltimore, MD: CMS. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. *ESRD prospective payment system claims-based monitoring program.* Baltimore, MD: CMS.

Childers, C. P., J. Q. Dworsky, G. Kominski, et al. 2019. A comparison of payments to a for-profit dialysis firm from government and commercial insurers. JAMA *Internal Medicine* 179, no. 8 (August 1): 1136–1138.

DaVita. 2023a. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2022. https://app.quotemedia.com/data/downloadFiling?webmasterId=101533&ref=117273730&type=PDF&symbol=DVA&companyName=DaVita+Inc.&formType=10-K&dateFiled=2023-02-22&CK=927066.

DaVita. 2023b. DaVita Inc. 3rd quarter 2023 results. https://investors.davita.com/2023-11-07-DaVita-Inc-3rd-Quarter-2023-Results.

DaVita. 2023c. Q3 2020 earnings call transcript. November 8. https://finance.yahoo.com/news/davita-inc-nyse-dva-q3-224617518.html?guccounter=1.

DaVita. 2022a. Annual report 2021. Denver, CO: DaVita.

DaVita. 2022b. DaVita Inc. 3rd quarter 2022 results. https://investors.davita.com/2022-10-28-DaVita-Inc-3rd-Quarter-2022-Results.

DaVita. 2019. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2018.

Fresenius Medical Care. 2023a. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2022. https://www.sec.gov/ix?doc=/Archives/edgar/data/1333141/000110465923024168/fms-20221231x20f.htm.

Fresenius Medical Care. 2023b. Q3 2023 conference call. November 2. https://www.freseniusmedicalcare.com/en/investors/publications.

Fresenius Medical Care. 2022. Future Fresenius: Annual report 2022. https://www.fresenius.com/sites/default/files/2023-03/Fresenius_Annual_Report_2022_3.pdf.

Gold Kidney Health Plan. 2022. Gold Kidney Health Plan raises $60 million from Chicago Pacific Founders in partnership to serve patients with kidney diseases. https://goldkidney.com/gold-kidney-health-plan-raises-60-million-from-chicago-pacific-founders-in-partnership-to-serve-patients-with-kidney-diseases/.

Government Accountability Office. 2023. *CMS plans for including phosphate binders in the bundled payment.* GAO–24–10628. Washington, DC: GAO. September.

Gupta, N., E. B. Taber-Hight, and B. W. Miller. 2021. Perceptions of home dialysis training and experience among US nephrology fellows. *American Journal of Kidney Diseases* 77, no. 5 (May): 713–718 e711.

Landi, H. 2022. 3 kidney care providers—Fresenius Health Partners, Cricket Health and InterWell Health—plan to merge in deal valued at $2.4B. *Fierce Healthcare*, March 21. https://www.fiercehealthcare.com/providers/three-kidney-care-providers-fresenius-health-partners-cricket-health-and-interwell-health.

Lin, E., X. S. Cheng, K. K. Chin, et al. 2017. Home dialysis in the prospective payment system era. *Journal of the American Society of Nephrology* 28, no. 10 (October): 2993–3004.

Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2016. Comment letter on CMS's proposed rule on the ESRD prospective payment system, July 29.

Medicare Payment Advisory Commission. 2015. Comment letter to CMS on the ESRD prospective payment system and the ESRD Quality Incentive Program, August 6.

Medicare Payment Advisory Commission. 2014. Comment letter to CMS on the end-stage renal disease prospective payment system and quality incentive program proposed rule, August 15.

Melanson, T. A., J. M. Hockenberry, L. Plantinga, et al. 2017. New kidney allocation system associated with increased rates of transplants among Black and Hispanic patients. *Health Affairs* 36, no. 6 (June 1): 1078–1085.

Ochieng, N., J. Fuglesten Biniek, M. Freed, et al. 2023. *Medicare Advantage in 2023: Premiums, out-of-pocket limits, cost sharing, supplemental benefits, prior authorization, and star ratings.* Washington, DC: Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/.

Pravoverov, L. V., S. Zheng, R. Parikh, et al. 2019. Trends associated with large-scale expansion of peritoneal dialysis within an integrated care delivery model. *JAMA Internal Medicine* 179, no. 11 (November 1): 1537.

Satellite Healthcare. 2022. Satellite Healthcare and Dialyze Direct to enter strategic collaboration, expanding cutting edge dialysis services across U.S. https://www.satellitehealthcare.com/newsroom/satellite-healthcare-and-dialyze-direct-to-enter-strategic-collaboration.

United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2023. *USRDS 2023 annual data report.* Bethesda, MD: NIDDK. https://usrds-adr.niddk.nih.gov/2023.

Walker, D. R., G. W. Inglese, J. A. Sloand, et al. 2010. Dialysis facility and patient characteristics associated with utilization of home dialysis. *Clinical Journal of the American Society of Nephrology* 5, no. 9 (September): 1649–1654.