CHAPTER 5

Outpatient dialysis services

RECOMMENDATION

5 For calendar year 2027, the Congress should eliminate the update to the 2026 Medicare base payment rate for outpatient dialysis services.

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 2024, about 240,500 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 7,600 dialysis facilities. In 2024, the FFS Medicare program and its beneficiaries spent $7.6 billion for outpatient dialysis services.

Assessment of payment adequacy

Our payment-adequacy indicators for outpatient dialysis services were generally favorable.

***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 is generally favorable.

- ***Capacity and supply of providers*—**The capacity of dialysis facilities appears to be aligned with demand from Medicare beneficiaries on dialysis. Between 2023 and 2024, the number of in-center treatment stations declined, but so did the number of Medicare beneficiaries on dialysis enrolled in either FFS Medicare or Medicare Advantage (MA). In addition, over the last decade (2012 to 2022), the growth in the number of patients newly diagnosed with ESRD (across all insurance

In this chapter

types) slowed. Between 2023 and 2024, the share of FFS beneficiaries dialyzing at home continued to increase.

- ***Volume of services*—**The 8 percent decline in FFS treatments between 2023 and 2024 is largely due to the shift of beneficiaries on dialysis from FFS Medicare to MA, after the removal of a statutory provision that had prevented most beneficiaries on dialysis from enrolling in MA plans. The share of beneficiaries on dialysis enrolled in FFS Medicare fell by 18 percent between 2020 and 2021—the first year of the statutory change—and by about 12 percent annually between 2021 and 2023, and by 7 percent between 2023 and 2024. Although the number of FFS beneficiaries on dialysis and treatments declined between 2023 and 2024, the average number of dialysis treatments per FFS beneficiary per week remained steady at 2.8. At the same time, the per treatment use of ESRD drugs in the payment bundle (including selected erythropoiesis-stimulating agents used in anemia management) has continued to decline since 2010 with little to no measurable impact on beneficiaries' health outcomes.

***Quality of care*—**Between 2023 and 2024, fluid management (as measured by dialysis adequacy) and anemia management of FFS beneficiaries on dialysis remained steady, as did rates of all-cause hospitalization, but emergency department use increased. While the mortality rate among FFS beneficiaries on dialysis was steady between 2023 and 2024, it remained elevated compared with prepandemic rates (2019). Measures of patient experience with receiving in-center hemodialysis remained steady. The share of FFS beneficiaries dialyzing at home, which is associated with greater 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. The two largest dialysis organizations (which accounted for three-quarters of facilities and FFS Medicare treatments in 2024) have continued to grow through acquisitions of and mergers with midsize dialysis organizations. In 2024 and 2025, facility closures and consolidations by each of the two largest dialysis organizations aimed to reduce unused capacity related to the increasing use of home dialysis and the decline in patient census in some markets.

***FFS Medicare payments and providers' costs*—**Between 2023 and 2024, 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 declined by 3 percent. In 2024, a decline in cost growth was observed across overhead and ESRD-drug cost categories. Consequently, the FFS Medicare margin rose from −0.2 percent in 2023 to 4.5 percent in 2024. We project a 2026 FFS Medicare margin of 4 percent. This projection does not account for the add-on payments for new ESRD drugs and phosphate binders in 2025 and 2026, which may increase FFS Medicare payments relative to facilities' costs.

How should FFS Medicare payments change in 2027?

Under current law, the FFS Medicare base payment rate for dialysis services is projected to increase by 1.6 percent in 2027. Given that most of our indicators of payment adequacy are positive, the Commission recommends that, for calendar year 2027, the Congress eliminate the update to the 2026 base payment rate. ■

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 patients on dialysis 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 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. ■

As required by law, the Commission annually makes payment-update recommendations for providers paid under Medicare's traditional fee-for-service (FFS) payment systems. Such providers include dialysis facilities that provide outpatient dialysis services to FFS beneficiaries with end-stage renal disease (ESRD), the last stage of chronic kidney disease (CKD), which is characterized by permanent, irreversible kidney failure.

Background

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 patients with ESRD undergo maintenance dialysis (see text box on dialysis treatment choices).[1] 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 that result from the loss of kidney function.

About 7,600 dialysis facilities provided outpatient dialysis services to 240,500 FFS beneficiaries in 2024. The dialysis sector is highly consolidated, with two large dialysis organizations (LDOs)—Fresenius Medical Care and DaVita—dominating the industry. In 2024, these LDOs accounted for three-quarters of facilities and FFS Medicare treatments. Moreover, in 2024, the five largest dialysis organizations accounted for roughly 86 percent of facilities and 88 percent of FFS Medicare treatments.

Medicare pays facilities that provide dialysis services to FFS beneficiaries using a prospective payment system (PPS) bundle that includes ESRD drugs and services, such as laboratory services.[2,3] The unit of payment is a dialysis treatment; FFS Medicare's payment rate is based on a regimen of three dialysis treatments per week. In 2024, the FFS Medicare program and its beneficiaries spent $7.6 billion for outpatient dialysis services. This total includes roughly $37 million in add-on payments associated with new ESRD drugs (Korsuva, Jesduvroq, and DefenCath). Additionally, in 2023 (the most recent year of data available), Part D

TABLE 5–1

FFS beneficiaries on dialysis are disproportionately young, male, and Black or Hispanic compared with other FFS beneficiaries, 2024

	Share of FFS beneficiaries	
	Beneficiaries on dialysis	**Other beneficiaries**
Age		
Under 45 years	10%	3%
45–64 years	31	7
65–74 years	29	47
75–84 years	23	32
85+ years	7	12
Sex		
Male	58	45
Female	42	55
Race		
White	45	81
Black	27	7
Hispanic	16	5
Asian	6	3
All others	6	4
Residence, by type of county		
Urban	84	80
Micropolitan	9	11
Rural, adjacent to urban	4	5
Rural, not adjacent to urban	2	4

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 based on an aggregation of the Urban Influence Codes. Components 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, 2024.

gross spending for ESRD oral-only drugs that had not yet been included in the PPS—several phosphate binders—totaled nearly $0.6 billion for FFS beneficiaries on dialysis.

Characteristics of fee-for-service beneficiaries on dialysis, 2024

Compared with other FFS Medicare beneficiaries, FFS beneficiaries on dialysis are disproportionately young (under 65), male, and Black or Hispanic (Table 5-1). In 2024, 41 percent of FFS beneficiaries on dialysis were under 65 years old, 58 percent were male, 27 percent were Black, and 16 percent were Hispanic. By comparison, among other FFS Medicare beneficiaries, 10 percent were under 65 years old, 45 percent were male, 7 percent were Black, and 5 percent were Hispanic. A greater share of FFS beneficiaries on dialysis resided in urban areas compared with other FFS beneficiaries (84 percent vs. 80 percent).

FFS beneficiaries on dialysis are more likely than all other FFS beneficiaries to have full Medicaid benefits

(33 percent vs. 11 percent) (data not shown). FFS Part D enrollees on dialysis are more likely to receive the low-income subsidy than all other FFS Part D enrollees (58 percent vs. 21 percent). We estimate that roughly 59,000 FFS Medicare beneficiaries began dialysis in 2024 (a 2 percent increase compared with 2023).

Medicare pays for dialysis services under the fee-for-service ESRD prospective payment system

To treat ESRD, beneficiaries on dialysis receive care from two principal providers: (1) 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 beneficiaries on dialysis. 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 Innovative Renal Care and U.S. Renal Care, have established joint ventures with physicians (Xia et al. 2025).[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 it is not required to disclose such information to patients, researchers, or members of the public.

The Commission's payment-adequacy indicators pertain to Medicare's payments to 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. For adult beneficiaries on dialysis, the ESRD PPS base payment rate to dialysis providers does not differ by type of dialysis—in-center dialysis versus home dialysis (which is consistent with the Commission's principle that Medicare should pay the same amount for the same service, even when it is provided in different settings)—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).[6] Medicare pays facilities that furnish dialysis treatments in the facility or in a patient's home for up to three treatments per week, unless 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.[7] Effective January 1, 2025, CMS pays a transitional drug add-on payment adjustment (TDAPA) for oral-only phosphate binders at 100 percent of each product's Part B average sales price, plus a $36.41 per month flat rate to account for facilities' operational costs in furnishing these products; the TDAPA will be paid for at least two years. The two-year TDAPA for Jesduvroq (used to treat anemia) concluded on September 30, 2025, while the TDAPA for DefenCath (to reduce the incidence of catheter-related bloodstream infections) will end on June 30, 2026. Korsuva (an antipruritic) and DefenCath will be paid under a post-TDAPA for three years at the end of each drug's TDAPA period.[8,9,10] In 2024, no ESRD-related equipment or supply was paid for under the two-year transitional payment adjustment for new and innovative equipment and supplies (TPNIES).[11]

Are FFS Medicare payments adequate in 2026?

To address whether payments for 2026 are adequate to cover the costs to efficiently provide care and to determine how much payments should change in the update year (2027), 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 relative to demand. 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. The FFS Medicare margin rose from −0.2 percent in 2023 to 4.5 percent in 2024 because providers' cost per treatment dropped by

TABLE 5–2

The capacity of dialysis organizations declined between 2023 and 2024

	2024			Average annual percent change			
				2019–2023		2023–2024	
	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities	Number of stations	Number of facilities	Number of stations
All dialysis facilities	7,605	137,195	18	0.2%	1.1%	–1.4%	–1.0%
	Share of total						
Freestanding	96%	96%	18	0.4	1.2	–1.4	–1.0
Hospital based	4	4	14	–3.3	–2.7	–0.9	–0.1
Urban	84	87	19	0.5	1.3	–1.2	–0.8
Micropolitan	10	9	16	–0.7	–0.2	–1.6	–0.6
Rural, adjacent to urban	4	3	14	–3.3	–2.6	–1.3	–1.4
Rural, not adjacent to urban	2	1	12	–3.0	–1.9	0.6	1.0
For profit	90	91	18	0.7	1.5	–0.8	–0.3
Nonprofit	10	9	17	–3.3	–2.8	–6.8	–7.2
Two LDOs	74	75	18	0.1	1.1	–1.7	–1.1
All others	26	25	17	0.6	1.0	–0.7	–0.6

Note: FFS (fee-for-service), LDO (large dialysis organization (DaVita and Fresenius Medical Care)). "Location" reflects the type of county (urban, micropolitan, rural adjacent to urban, or rural nonadjacent to urban) in which the provider is located, based on an aggregation of the Urban Influence Codes. Components 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.

3 percent in 2024 and the FFS payment per treatment increased by 2 percent.[12]

Beneficiaries' access to care: Indicators continue to be positive

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 generally favorable.

Capacity is aligned with demand from Medicare beneficiaries on dialysis

In 2024, there were 7,605 dialysis facilities nationwide. FFS Medicare accounted for about 34 percent of all treatments furnished by freestanding providers.[13]

Between 2019 and 2023, growth in the number of dialysis facilities and in-center treatment stations exceeded growth in the number of patients on dialysis, across FFS Medicare and Medicare Advantage (MA). During that period, the number of facilities and their capacity to provide care—as measured by dialysis treatment stations—both grew, by 0.2 percent and 1.1 percent annually, respectively (Table 5-2). By comparison, the number of Medicare beneficiaries on dialysis (in FFS Medicare and MA combined) declined by 1 percent per year between 2019 and 2023 (data not shown).

Between 2023 and 2024, however, the number of facilities' in-center treatment stations declined by 1 percent while the number of beneficiaries on dialysis, across FFS Medicare and MA, also declined by 1 percent.

The decline in capacity may have been in response to declining demand attributable to factors such as the following:

- Excess mortality in the population of patients with ESRD, in part due to the coronavirus pandemic and the flu. Both LDOs reported in 2024 that mortality was elevated relative to prepandemic levels, exceeding the companies' forecast estimates (DaVita 2025c, DaVita 2024c, Fresenius Medical Care 2024a).
- Slower growth in the number of individuals newly diagnosed with ESRD (which includes patients with all types of health coverage who initiate dialysis or receive a kidney transplant) (United States Renal Data System 2024). Based on the most recent decade of data that are available (2012 to 2022), the number of patients newly diagnosed with ESRD increased on average by 2 percent per year between 2012 and 2017. By contrast, between 2017 and 2022, the growth in the number of newly diagnosed patients with ESRD grew by only 0.5 percent per year.
- An increase in the use of home dialysis, which has reduced the demand for in-facility treatments. The share of FFS beneficiaries dialyzing at home steadily increased from 9 percent per month in 2011 (the first year of the ESRD PPS) to 17 percent per month in 2023 and 18 percent per month in 2024. Based on data from FFS Medicare claims, the share of facilities offering home dialysis remained steady in 2023 and 2024, ranging from 56 percent to 57 percent. In addition, through 2025, the CMS Innovation Center's mandatory ESRD Treatment Choices (ETC) Model rewarded dialysis facilities and clinicians who were part of the model for increasing home dialysis use and kidney transplantation among adult beneficiaries on dialysis and penalized facilities and clinicians who were not.[14]

In response to lower patient census in some markets and increasing use of home dialysis, the two LDOs have closed and merged some of their facilities in recent years. Between 2023 and 2024, the total number of facilities operated by the two LDOs declined by 0.2 percent (DaVita 2024a, DaVita 2022b, Fresenius Medical Care 2024b). Closing or merging facilities can improve efficiency by, for example, consolidating management and saving on fixed expenses such as rent and medical-director fees (DaVita 2024b).

For-profit, freestanding facilities provide most dialysis treatments: In 2024, freestanding facilities furnished 95 percent of FFS treatments, and for-profit facilities furnished 91 percent (data not shown). Between 2023 and 2024, capacity (as measured by the number of in-center stations) fell at freestanding facilities by 1 percent and at for-profit facilities by roughly 0.3 percent, while capacity at nonprofit facilities fell by roughly 7 percent (Table 5-2).

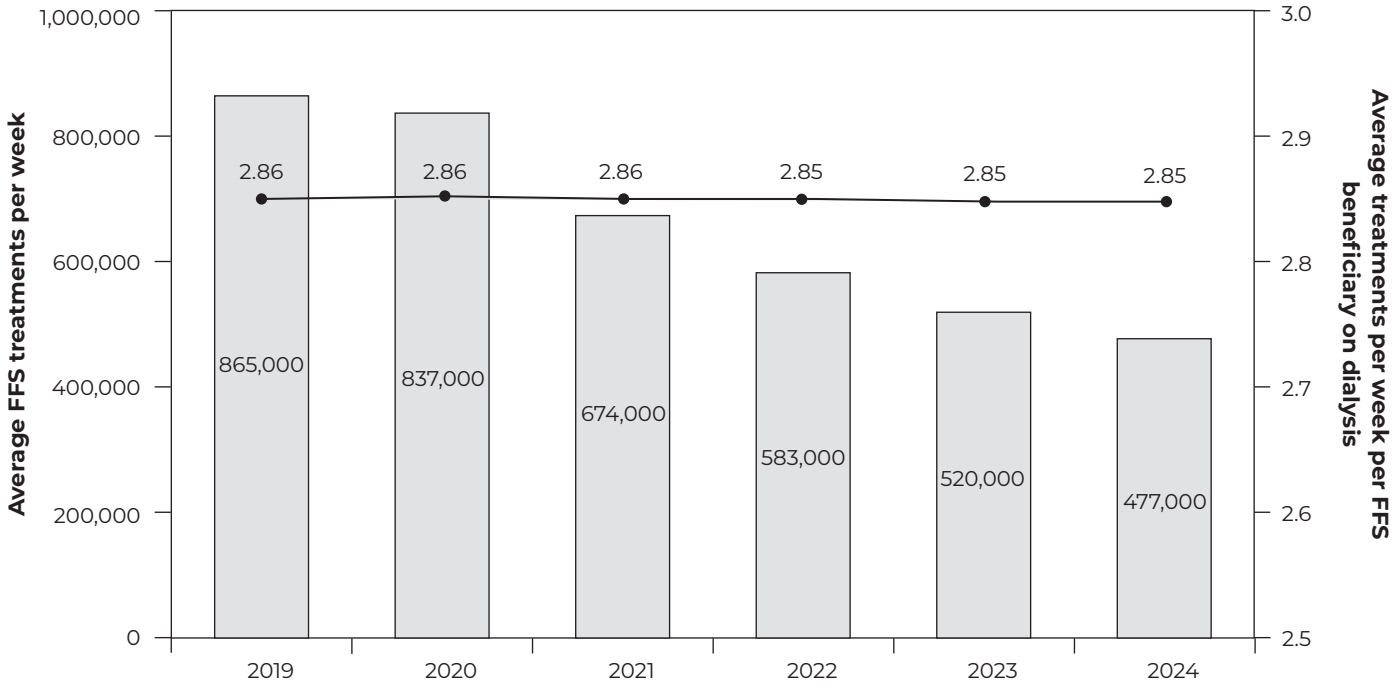
The capacity of facilities in urban and rural areas in 2024 was generally consistent with where FFS beneficiaries on dialysis lived: 87 percent of FFS treatments were provided in urban areas, and 87 percent of dialysis stations were located in urban areas. Between 2023 and 2024, capacity at urban facilities declined by 0.8 percent while capacity at all rural facilities declined by 0.6 percent.

We find that in 2024, rural facilities and low-volume facilities—which are smaller and furnish fewer total treatments than all facilities—are more likely to be hospital based and nonprofit. Specifically, compared to all facilities, rural facilities were more likely to be hospital based (9 percent vs. 4 percent) and nonprofit (16 percent vs. 10 percent), with roughly similar shares of LDOs and non-LDOs (72 percent vs. 74 percent) in 2024. In addition, compared to all facilities, the roughly 300 facilities that received the ESRD PPS's low-volume payment adjustment (LVPA) in 2024 were more likely to be nonprofit (25 percent vs. 10 percent), hospital based (16 percent vs. 4 percent) and non-LDOs (45 percent vs. 26 percent) (data not shown).

In June 2020, the Commission recommended that the Secretary replace the ESRD PPS's LVPA and rural adjustment with a single payment adjustment—a low-volume and isolated adjustment—to better support isolated, low-volume dialysis facilities that are critical to ensuring beneficiary access (Medicare Payment Advisory Commission 2020b). Instead, in the ESRD PPS final rule for 2025, CMS modified the LVPA policy by creating two-tiered adjustments for ESRD facilities: one adjustment for facilities that furnish fewer than 3,000 treatments and one for facilities that furnish between 3,000 and 3,999 treatments. CMS did not change the

FIGURE 5–1

Though the average number of weekly FFS treatments declined, the average number of FFS dialysis treatments per beneficiary per week remained steady, 2019–2024



Note: FFS (fee-for-service).

Source: Data compiled by MedPAC from claims submitted by dialysis facilities to CMS, 2019–2024.

current 0.8 percent rural-facility adjustment (Centers for Medicare & Medicaid Services 2024c).

Between 2021 and 2024, the share of beneficiaries on dialysis in FFS Medicare declined since the lifting of the prohibition on MA enrollment in 2021

Historically, Medicare beneficiaries with ESRD generally had traditional FFS coverage because they were largely prohibited from enrolling in MA plans, with a few exceptions (see text box on beneficiaries on dialysis enrolled in MA plans, pp. 164–165). Beginning in January 2021, a statutory change allowed beneficiaries on dialysis to enroll in any MA plan. Subsequently, the number of FFS beneficiaries on dialysis fell 10 percent per year from 2021 through 2024. By December 2024, just 45 percent of Medicare beneficiaries on dialysis were enrolled in FFS.

As FFS enrollment declined among beneficiaries on dialysis, the total number of FFS treatments fell 11 percent per year between 2021 and 2024.[15] However, the number of dialysis treatments per beneficiary per week remained steady, ranging from 2.8 to 2.9 between 2019 and 2024, indicating that FFS beneficiaries with ESRD continue to have access to dialysis services (Figure 5-1).[16]

Use of most ESRD drugs has declined, with little impact on beneficiaries' outcomes

Under the ESRD payment method used before 2011, certain ESRD drugs were paid according to the number of units of the drug administered; thus, the more units of a drug were provided, the higher Medicare payments were. 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 drugs that were previously billed separately.

TABLE 5–3

Under the ESRD PPS, use of ESRD drugs per treatment has declined, partly attributable to the shift to less costly, clinically similar products

	Pre–ESRD PPS use of ESRD drugs weighted by constant prices*	Percent of aggregate change between:		
Drug group	**2010**	**2010–2011**	**2010–2024**	**2023–2024**
ESAs	$45	–23%	–69%	–4%
Iron agents	4	–7	–22	–2
Vitamin D agents	2	–20	–80	–19
Calcimimetics	N/A**	N/A	N/A	–6
Other drugs	2	–43	–85	–1
All drug groups above	53	–22	–54	–5

Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not available). The ESRD PPS began in 2011. ESAs include epoetin alfa reference, epoetin alfa biosimilar, epoetin beta, and darbepoetin. Iron agents include iron sucrose and sodium ferric gluconate. Vitamin D agents include calcitriol, doxercalciferol, and paricalcitol. Calcimimetics include 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. This analysis includes ESRD drugs paid under the ESRD PPS base rate in 2024.
* To estimate drug use by therapeutic class, we weight use (i.e., drug units) by constant prices. That is, we hold the price of each drug constant and multiply drug units reported on claims in a given year by 2024 average sales price (ASP) plus 0 percent. Because 2024 ASP data are not available for cinacalcet (a calcimimetic), we used the payment limit for CMS's transitional drug add-on payment adjustment for the fourth quarter of 2020 and updated it to 2024 dollars using the pharmaceutical Producer Price Index (PPI). Because 2024 ASP data are not available for calcitriol (a vitamin D agent), we used average 2023 ASP data and updated them to 2024 dollars using the pharmaceutical PPI. By holding the price constant, we account for the different billing units assigned to a given drug.
** Since 2021, calcimimetics have been paid under the ESRD PPS base rate. Thus, utilization data under the ESRD PPS are not available for 2010.

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

Table 5-3 shows changes between 2010 and 2024 (the most current year for which complete data are available) in the per treatment use of the leading ESRD drugs, which we aggregate into five therapeutic groups: erythropoiesis-stimulating agents (ESAs), iron agents, calcimimetics, vitamin D agents, and other products.[17] We estimated per treatment use by multiplying ESRD drug units per treatment reported on CMS claims by each drug's 2024 average sales price (ASP) plus 0 percent; that is, we estimated the use of drugs weighted by constant prices.[18] Thus, the change in our measure of drug use over time reflects shifts in the intensity of ESRD drugs prescribed to FFS beneficiaries on dialysis, which could reflect a combination of effects, such as changes in the (1) mix of drugs within a given therapeutic group furnished to beneficiaries, (2) share of beneficiaries receiving any ESRD drug in the five therapeutic groups, and (3) dose per treatment of a given drug.

As shown in Table 5-3, 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 example, between 2010 and 2011, ESRD drug use per treatment across all therapeutic classes declined by 23 percent. Most of this overall decline was due to lower 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 lead to increased risk of morbidity and mortality, which resulted in the Food and Drug Administration (FDA) changing the ESA label in 2011.

Most recently, between 2023 and 2024, holding price constant, use across the five therapeutic groups declined by 5 percent; this decline partly reflects changes in the dose per treatment furnished to beneficiaries as well as the shift to less costly, clinically

The majority of beneficiaries on dialysis are now enrolled in MA plans

Although individuals with end-stage renal disease (ESRD) have been entitled to Medicare Part A and Part B benefits since 1972, they were mostly prohibited from joining Medicare Advantage (MA) plans until 2021: Beneficiaries could enroll in a plan specifically designed for enrollees with ESRD, and those beneficiaries who had enrolled in MA before being diagnosed with ESRD could stay in the plan after they were diagnosed. In 2000, the Commission recommended that the Congress lift the bar prohibiting ESRD beneficiaries from enrolling in MA (Medicare Payment Advisory Commission 2000). Beginning in January 2021, the 21st Century Cures Act permitted beneficiaries on dialysis to enroll in any MA plan. The share of beneficiaries on dialysis enrolled in MA plans has since increased rapidly, from 27 percent in December 2020 to 55 percent by December 2024.

The increase in MA enrollment by beneficiaries on dialysis is likely linked to the same factors that have increased MA's popularity among beneficiaries without ESRD, including the availability of supplemental benefits (e.g., dental, hearing, and vision services) and lower cost-sharing liability. For beneficiaries, the primary trade-off in choosing between MA and FFS Medicare is access to the additional benefits that plans provide versus a broader choice of providers participating in FFS Medicare. In exchange for additional benefits, MA plan enrollees accept provider networks and utilization-management tools such as higher cost sharing to access providers who are not in their plan's network. A 2021 policy change by CMS that excludes outpatient dialysis facilities from the list of specialty providers subject to Medicare's network-adequacy evaluation could affect access for some MA beneficiaries on dialysis. If MA plans include fewer dialysis facilities in their network, travel time for some MA beneficiaries to a dialysis facility could be affected. (See the Commission's comment letter on changes to the MA program for contract year 2021 for more discussion about proximity to a dialysis facility and dialysis care (Medicare Payment Advisory Commission 2020a).)

Given the magnitude of total health care expenses incurred annually by beneficiaries on dialysis (for dialysis and other outpatient and inpatient services

(continued next page)

similar products within a therapeutic group. For example, the share of FFS beneficiaries on dialysis who received epoetin beta increased between 2023 and 2024. This increase is linked to the transition by one LDO's patients from epoetin alfa to epoetin beta (DaVita 2022b). Thus, among the four ESA products in 2023 and 2024, use (as measured by units per treatment) of epoetin beta increased, while use of darbepoetin, epoetin alfa reference product, and epoetin alfa biosimilar declined. The Commission has previously reported other shifts over time in the use of ESAs and vitamin D agents (paricalcitol, doxercalciferol, and calcitriol) due to price competition among the products in each category (Medicare Payment Advisory Commission 2022).

Some of the change in ESRD drug use between 2023 and 2024 also reflects changes in the share of FFS beneficiaries on dialysis receiving an ESRD drug. Overall, the share of FFS beneficiaries on dialysis prescribed drugs to treat anemia—ESAs and iron agents—each declined by 1 percentage point between 2023 and 2024, while the share of beneficiaries prescribed drugs that treat bone and mineral metabolism disorders—calcimimetics and vitamin D agents—remained stable and declined by 2 percentage points, respectively. 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

The majority of beneficiaries on dialysis are now enrolled in MA plans (cont.)

and Part D drugs—averaging nearly $106,000 in 2023, with beneficiary out-of-pocket liability averaging nearly $14,000), these beneficiaries face significant out-of-pocket expenses when they are enrolled in FFS Medicare with no secondary or supplemental coverage. Thus, they might enroll in MA because MA plans are required by statute to offer a maximum out-of-pocket (MOOP) limit on annual spending that is not available in FFS Medicare. The mandatory MOOP limit was $9,350 for in-network services in 2025 (and $14,000 for in- and out-of-network services covered by preferred provider organizations). Beneficiaries who have full Medicaid coverage, as well as qualified Medicare beneficiaries with partial dual eligibility, have their cost sharing covered by Medicaid but may still find it desirable to enroll in an MA plan for the supplemental benefits offered.

Beneficiaries who do not have their cost sharing covered by Medicaid and prefer 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. Among FFS beneficiaries without cost sharing covered by Medicaid, those on dialysis are less likely to purchase a Medigap plan than FFS beneficiaries who are not on dialysis (31 percent vs. 50 percent in 2024)[19] 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.[20]
- The affordability of a Medigap plan. Even though beneficiaries with ESRD who are under 65 must be offered at least one Medigap plan in 36 states, the insurer can charge a higher premium based on age, sex, or existing health conditions, depending on state insurance-rating rules.[21] ■

program has revealed no sustained decline of beneficiary health status from January 2010 through December 2023 (Centers for Medicare & Medicaid Services 2023a).[22]

Quality of outpatient dialysis care is mixed

In 2023 and 2024, measures of dialysis adequacy and anemia management (hemoglobin levels) and blood transfusion rates remained generally stable. Hospitalization rates remained stable among FFS beneficiaries on dialysis, but use of the emergency department (ED) increased. Mortality rates remained stable between 2023 and 2024 but have remained elevated compared with before the coronavirus pandemic. In-center hemodialysis patient-experience measures also remained steady. Use of home dialysis and the number of kidney transplants increased during this period.[23]

Quality under the ESRD PPS

We use available claims and enrollment data for FFS beneficiaries on dialysis to assess process and outcome measures associated with the quality of outpatient dialysis care. Process measures include dialysis adequacy and anemia management, and outcome measures include rates of mortality, hospitalizations, and ED visits.

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, the share of beneficiaries receiving adequate dialysis remained steady between 2021 and 2024, averaging between 97 percent and 98 percent of beneficiaries on hemodialysis and between 92 percent and 93 percent of beneficiaries receiving peritoneal dialysis (PD) at home. There was little difference between rural and urban areas in the share of beneficiaries on hemodialysis and PD receiving adequate dialysis.

We assess the quality of anemia management by examining changes over time in (1) beneficiaries' hemoglobin levels, as assessed by a blood test that measures the level of hemoglobin (the protein that carries oxygen in red blood cells); and (2) frequency of red blood cell transfusions.[24] 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 grams per deciliter (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 2021 and 2024, median hemoglobin levels remained constant, averaging 10.5 g/dL. During this period, the share of FFS beneficiaries on dialysis with lower (less than 10 g/dL) and higher (exceeding 12 g/dL) hemoglobin levels remained steady, averaging 31 percent and 6 percent of beneficiaries, respectively. There was little difference in the hemoglobin status of beneficiaries on dialysis residing in rural versus urban areas. Between 2021 and 2024, the share of beneficiaries treated with a blood transfusion remained relatively steady, averaging between 2.7 percent and 2.8 percent per month.

As for outcome measures of mortality, hospitalizations, and ED visits:

- In 2020, as the coronavirus pandemic took hold, mortality averaged 1.9 percent per month, up from an average of 1.6 percent in 2019. The rate of mortality per month remained elevated, averaging about 2.0 percent per month in 2021 through 2024.
- Between 2021 and 2024, the share of FFS beneficiaries on dialysis who were admitted to a short-stay hospital (beneficiaries with at least one admission in a given month) remained relatively steady, averaging 14 percent to 15 percent per month. During the same period, 30-day readmission rates on an annual basis remained relatively steady at 21 percent of admissions.[25]
- Between 2021 and 2023, the share of FFS beneficiaries on dialysis who used the ED (beneficiaries with at least one ED visit in a given month) averaged around 18 percent per month and increased to 20 percent in 2024.

Patient-experience measures

The In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH–CAHPS) survey provides patient ratings of their dialysis facility, center staff, and nephrologist for their communications, care, operations, and provision of information (Centers for Medicare & Medicaid Services 2024a). Among survey respondents, roughly 60 percent to 80 percent gave the top ratings across the six measures we examined (Table 5-4). Survey results did not differ between urban and rural facilities (data not shown). Patient experience remained relatively stable between reporting years 2023 and 2025, but there remains room for improvement. In particular, the global rating of nephrologists consistently scored the lowest, with only 60 percent of patients giving their nephologist a rating of 9 or 10 out of 10 (best possible) in 2025. Per the 2026 ESRD PPS final rule, however, CMS is removing from the ICH-CAHPS all measures related to rating nephrologists (e.g., nephrologists' communication and caring, and rating of the nephrologist) (Centers for Medicare & Medicaid Services 2025b).[26]

Access to home dialysis

Researchers have concluded that the ESRD PPS, which began in 2011, is associated with an overall increase in the use of home dialysis (Lin et al. 2017).[27] The share of beneficiaries dialyzing at home steadily increased from 9 percent per month in 2011 to 18 percent per month in 2024. Differences by race have persisted over time: Although about 27 percent of FFS Medicare beneficiaries with ESRD on dialysis are Black, they represent only 23 percent of beneficiaries who dialyze at home.

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 of treatment options, as well as

TABLE 5–4

In-center hemodialysis patient-experience scores, 2023–2025

ICH–CAHPS measures	2023	2024	2025
Share of patients giving top ratings for:			
Nephrologists' communication and caring	67%	67%	67%
Quality of dialysis center care and operations	64	64	65
Providing information to patients	79	79	80
Share of patients rating a 9 or 10 out of 10 (best possible):			
Rating of the nephrologist	59	59	60
Rating of the dialysis center staff	64	65	66
Rating of the dialysis facility	69	69	70

Note: ICH–CAHPS (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems). The ICH–CAHPS is a survey of patient experiences with the dialysis facility, facility doctors and staff, and care received. The survey's measures included in the table are "top box," or the most positive, response to ICH–CAHPS survey items. The first three measures are composite measures of multiple survey questions that have responses of "never," "sometimes," "usually," and "always." Share of patients giving top ratings include those who reported "always." Survey results are publicly reported twice a year, based on data from the two most recent survey periods. Each year, spring survey data are collected from April through July and fall survey data are collected from November through January. The years indicate reporting years: Data for reporting year 2025 include surveys collected from the 2024 spring and 2024 fall surveys. Among facilities reporting ICH–CAHPS data (2,363 facilities in reporting year 2025), the survey-response rate was, on average, 27 percent.

Source: CMS summary of national average for ICH–CAHPS survey measures, 2023–2025.

physicians' training and preference). For example, nephrology trainees have 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).[28] Some clinical and nonclinical factors affecting use of home dialysis are amenable to intervention. For example, between 2008 and 2018, under an integrated care delivery system (Kaiser Permanente Northern California), PD use among patients new to dialysis 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 is associated with lower Medicare spending. In 2021, average annual Medicare spending for patients on dialysis (roughly $105,000) was more than twice the annual spending for those who had a functioning kidney transplant (nearly $49,000 in 2022) (United States Renal Data System 2024). However, demand for kidney transplantation exceeds the supply of available kidneys. Besides donation rates, factors that can 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; transplant-center policies; and, specific to beneficiaries enrolled in MA, contracts between MA networks and transplant centers. On July 1, 2025, the CMS Innovation Center began the

Increasing Organ Transplant Access (IOTA) Model, a six-year mandatory model, intended to reduce Medicare expenditures and improve performance in kidney transplantation among participating kidney transplant hospitals (Centers for Medicare & Medicaid Services 2024b).

Between 2023 and 2024, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by about 2 percent, to 27,760 (Table 5-5).[29] 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). Between 2019 and 2024, there was a marginal increase in the share of transplants for Black and Hispanic patients (Table 5-5).[30]

Access to capital for most dialysis providers appears to be strong

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 2024, DaVita continued its investment in 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, and it increased its international footprint (DaVita 2025a).
- In 2024, DaVita Venture Group (a corporate venture arm 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 2025a).
- Fresenius received initial FDA 510(k) clearance for its high-volume hemodiafiltration (HVHDF) machine in 2024 (Food and Drug Administration 2024b). In 2025, the company received FDA clearance for an updated machine that includes additional features that allow access to providers' medical information systems directly at chairside (Food and Drug Administration 2025). In 2025, the company announced the second phase of the company's efforts to introduce HVHDF kidney-replacement therapy across the U.S., which includes offering HVHDF therapy in its U.S. Fresenius Kidney Care dialysis clinics; they also announced that the full-scale commercial launch is anticipated in 2026 (Fresenius Medical Care 2025c).

In recent public financial filings, the two LDOs reported generally positive financial performance related to their dialysis business for 2025, including improvements in productivity (DaVita 2025c, Fresenius Medical Care 2025b). Other positive results recently reported by the LDOs as of the third quarter of 2025 include positive U.S. same-market treatment growth and strong organic revenue growth by Fresenius and DaVita's third-quarter performance, in line with the latter company's expectations to achieve full-year guidance (DaVita 2025d, Fresenius Medical Care 2025b).

Since 2010, both LDOs have grown through large acquisitions of and mergers with other dialysis facilities and 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 also entered into value- and risk-based programs with private payers to provide care to commercial and MA patients with ESRD and CKD. 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 the CMS Innovation Center's current Kidney Care Choices Model.

The two LDOs, in addition to operating three-quarters of all dialysis facilities, are both vertically integrated (DaVita 2023, Fresenius Medical Care 2023). For example, other health care services that one or both LDOs operate include an ESRD-related

TABLE 5–5 **The number of kidney transplants has increased**

	2019	2023	2024
Total transplants	23,401	27,332	27,760
Share of total transplants from live donors	29%	23%	23%
Share receiving a transplant			
White	45	40	39
Black	27	30	30
Hispanic	19	20	20
Asian	7	8	7
All others	2	2	3

Note: Individuals receiving a kidney transplant include individuals with end-stage renal disease 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. Components may not sum to 100 percent due to rounding.

Source: Organ Procurement and Transplantation Network.

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 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. For example, this LDO 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 patients on dialysis. In 2023, Part D spending on Velphoro for FFS beneficiaries on dialysis was nearly $237 million. 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. (See the text box in Chapter 2 on the different margin measures MedPAC uses to assess provider profitability, p. 55.) Using cost-report data submitted by freestanding dialysis facilities to CMS, we estimated that the 2024 all-payer margin was roughly 16 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.[31] Although commercial payment rates vary, average rates established under commercial contracts are generally significantly higher than Medicare rates. According to one LDO, in 2024, patients with commercial coverage (including hospital dialysis services) accounted for 11 percent of its U.S. patients on dialysis but about 33 percent of its U.S. dialysis revenues, while patients with government coverage accounted for 89 percent of its U.S. patients on dialysis and 67 percent of its U.S. revenues (DaVita 2025a). Similarly, researchers found that in 2017, the median MA payment for dialysis was 27 percent above FFS rates, and the payments were higher

to LDOs than to regional chains and independently owned dialysis facilities (Lin et al. 2022).

Medicare payments and providers' costs: Lower cost growth contributed to increase in FFS Medicare margin in 2024

Between 2023 and 2024, Medicare's payments per FFS dialysis treatment increased 2 percent, while total costs per treatment declined by 3 percent. In 2024, the FFS Medicare margin rose to 4.5 percent from −0.2 percent in 2023. (See the text box in Chapter 2 on the different margin measures MedPAC uses to assess provider profitability.)

Medicare payments for outpatient dialysis services

Between 2023 and 2024, FFS per capita annual spending for outpatient dialysis services for FFS beneficiaries (i.e., for dialysis treatments furnished by ESRD freestanding and hospital-based facilities) remained steady at nearly $31,000. Total FFS Medicare spending for these services, however, declined 6 percent from 2023, to $7.6 billion. As discussed earlier in the chapter, the decline is predominantly due to MA plans' increasing enrollment of beneficiaries on dialysis beginning in 2021. A statutory update (of 2 percent) increased the ESRD PPS base payment rate in 2024.

Between 2022 and 2023, Part D spending for ESRD oral-only phosphate binders declined for FFS beneficiaries on dialysis

Phosphate binders were the last oral-only drug group that were included in the ESRD PPS bundle in 2025 (the inclusion of oral-only drugs in the ESRD PPS bundle has been delayed by regulation and statute). The most current data that we have on the use of these products are from 2023, when they were covered under Part D. Between 2022 and 2023, spending for phosphate binders furnished to FFS beneficiaries on dialysis declined by 16 percent to $0.6 billion.[32] The decline in total FFS spending for phosphate binders for beneficiaries on dialysis is linked to the substantial decrease in beneficiaries on dialysis in FFS as enrollment shifted to MA beginning in 2021. Among FFS beneficiaries on dialysis who used phosphate binders, per capita spending between 2022 and 2023 declined by 5 percent to $4,300 per patient. Similar shares (ranging from 65 percent to 66 percent) of FFS beneficiaries on dialysis with Part D coverage were prescribed phosphate binders in 2022 and 2023, and phosphate binders accounted for 29 percent to 32 percent of their Part D spending. 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, phosphate binders are paid for under the ESRD PPS.[33] Dialysis facilities receive a TDAPA payment based on 100 percent of each product's ASP plus a fixed-rate addition of $36.41 per monthly claim for at least two years (2025 and 2026).[34] CMS derived the fixed-rate addition of $36.41 based on the weighted average of Medicare expenditures for phosphate binders per month under Part D, using utilization patterns in 2023 among Part D–eligible beneficiaries. According to the agency, the monthly fixed-rate addition approximates 6 percent of ASP and is intended to offset the incremental operational cost incurred by dialysis facilities in storing, managing, and dispensing phosphate binders to patients because such costs were not addressed when the ESRD PPS base rate was implemented in 2011 (Centers for Medicare & Medicaid Services 2024c).

Providers' costs for outpatient dialysis services under the ESRD PPS

We examine aggregate dialysis-facility costs using 2023 and 2024 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 2023 and 2024, total cost per treatment declined by 3 percent, from $291 per treatment to nearly $284 per treatment. The 3 percent decline in cost per treatment in 2024 relative to 2023 is attributable to a drop in cost per treatment for overhead and ESRD drugs, which was only partially offset by growth in other costs.

Costs fell for:

- overhead, by 13 percent, and accounted for 27 percent of cost per treatment in 2024; and

- ESRD drugs, by 15 percent, and accounted for 6 percent of providers' cost per treatment in 2024.

Costs increased for:

- labor, by 5 percent, and accounted for 37 percent of 2024 providers' cost per treatment;
- capital and supplies, which each increased by 2 percent and accounted for 18 percent and 11 percent of providers' cost per treatment, respectively; and
- laboratory services, by 1 percent, and accounted for 1 percent of 2024 providers' cost per treatment.

The 13 percent decline in overhead cost per treatment in 2024 contrasts with the relatively high cost growth of 9 percent per year between 2020 and 2023 (i.e., during the coronavirus pandemic). Our finding that ESRD drug costs declined in 2024 is attributable to the drop in the cost per treatment for ESAs. The continued decline in ESA costs is expected: Under the ESRD PPS (i.e., since 2011), ESA cost per treatment has declined on average by 10 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 2023 and 2024, average per treatment costs fell by 8 percent for facilities in the 25th percentile of cost growth, compared with a rise of 2 percent for facilities in the 75th percentile. The change in cost per treatment is related to facility size. Between 2023 and 2024, total cost per treatment for the smallest facilities (e.g., facilities furnishing fewer than 4,000 treatments) declined on average by 1 percent; by comparison, for all other facilities, total cost per treatment declined by 3 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 2024, labor and capital costs each varied by $40 per treatment. The Commission has 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).

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 a statistically significant relationship between the total number of treatments and cost per treatment (correlation coefficient equaled −0.5) in each year between 2019 and 2024 (Figure 5-2, p. 172). 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.

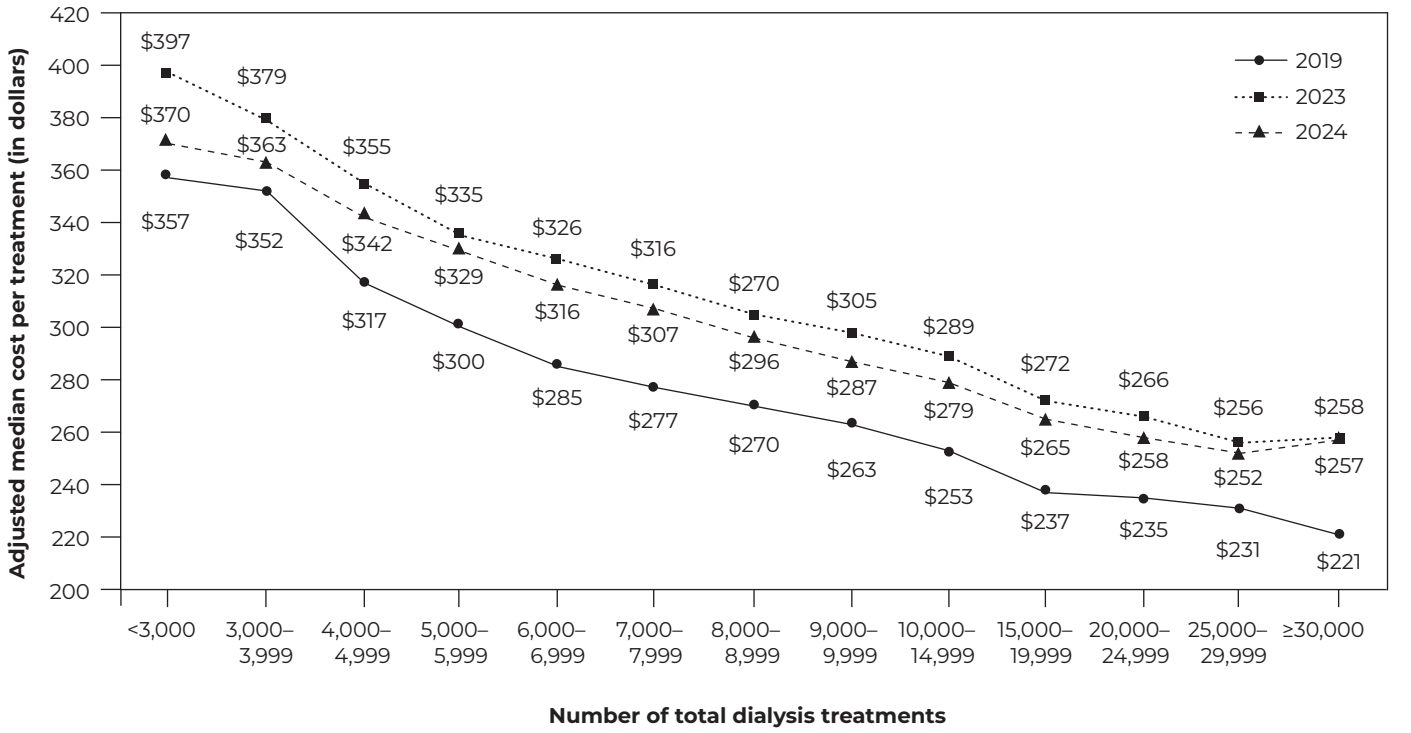
The trend in the FFS Medicare margin for freestanding dialysis facilities

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 2024.[35]

The FFS Medicare margin reached 8.4 percent in 2019 (the highest since the ESRD PPS was implemented in 2011)[36] but has since declined, falling to −1.1 percent in 2022 and −0.2 percent in 2023 (Figure 5-3, p. 173). Due to lower cost growth and a statutory update (of 2 percent), dialysis facilities' FFS Medicare margin rose in 2024, to 4.5 percent. While the margin has varied over time—including some periods in which it was negative or near zero and other periods where it was substantially positive—beneficiaries' access to care has remained positive throughout.

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 drugs (Figure 5-3, p. 173). During the initial years of the ESRD PPS, the FFS Medicare margin increased as providers furnished fewer ESRD drugs per treatment. Between 2014 and 2017, facilities' financial

FIGURE 5–2 **Higher-volume freestanding dialysis facilities had lower cost per treatment, 2019–2024**



Note: Cost per treatment is adjusted to remove geographic 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.

performance under FFS Medicare reversed, and the 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.

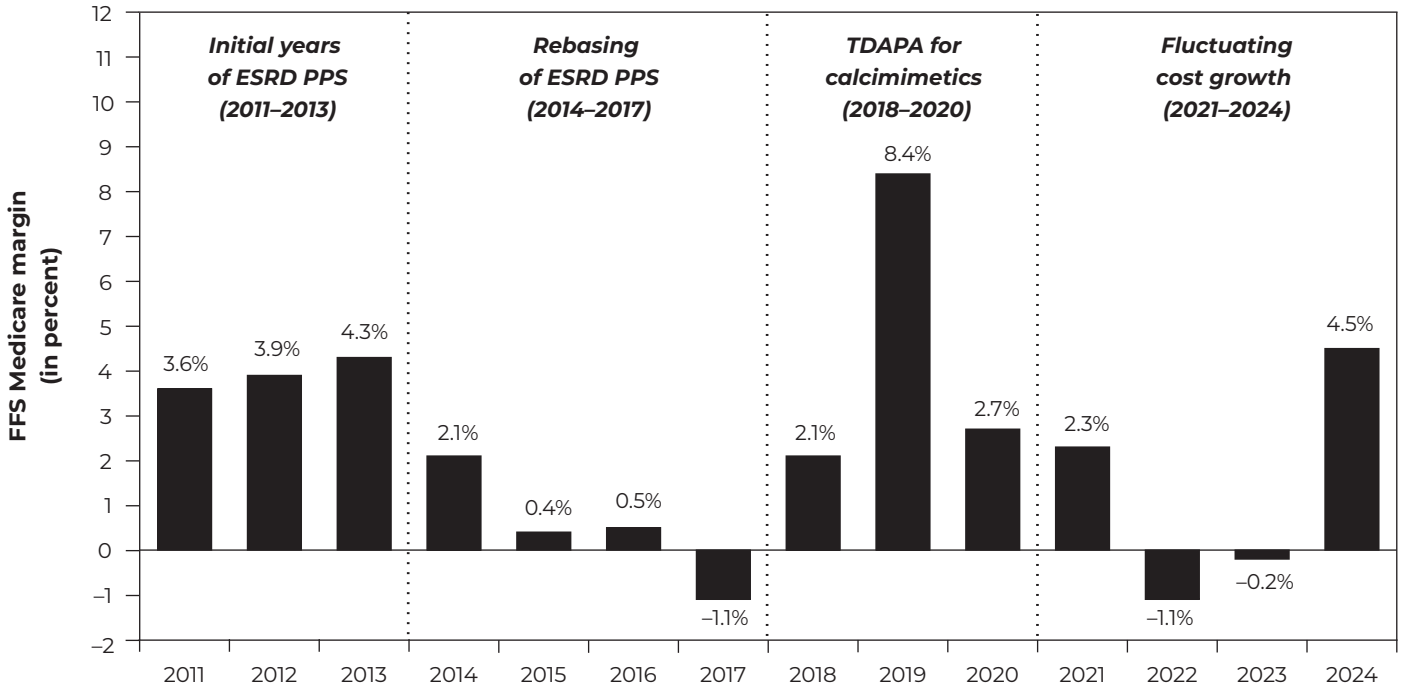
In 2018 and 2019, the FFS Medicare margin increased due to the profitability of calcimimetics paid under the TDAPA policy—to 2.1 percent in 2018 and 8.4 percent in 2019 (Figure 5-3).[37,38] In 2020, the FFS Medicare margin decreased to 2.7 percent (3.7 percent when including FFS Medicare's share of pandemic relief funds) because cost per treatment increased and the TDAPA payment for eligible drugs, including calcimimetics, declined from ASP plus 6 percent to ASP plus 0 percent. In 2021, the FFS Medicare margin declined again to 2.3 percent due to increasing cost per treatment for all cost categories except ESRD drug costs.

The FFS Medicare margin further declined to –1.1 percent in 2022, partly due to growth in labor and capital costs, which both increased by 7 percent between 2021 and 2022, well above the historical average. Due to lower cost growth and because growth in payment per treatment exceeded growth in cost per treatment, dialysis facilities' FFS Medicare margin rose in 2023, to –0.2 percent.

The increase in the FFS Medicare margin from –0.2 percent to 4.5 percent in 2024 is partly attributable to (1) lower overhead and ESRD-drug cost per treatment compared with 2023, and (2) the statutory update of the ESRD PPS base payment rate in 2024. Partially

FIGURE 5–3

FFS Medicare margin has varied over time



Note: FFS (fee-for-service), 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.

offsetting these factors were increases in the other cost categories, including labor and capital, between 2023 and 2024. In addition, the two LDOs experienced a 0.2 percent increase in total treatment volume (across all payers) between 2023 and 2024 (DaVita 2025a, Fresenius Medical Care AG 2025).

The FFS Medicare margin varies by treatment volume

FFS Medicare margins in 2024 decidedly varied by treatment volume: Facilities in the lowest-volume quintile had margins below –11 percent, while facilities in the top-volume quintile had margins of over 11 percent (Table 5-6, p. 175). Urban facilities averaged higher margins than rural facilities (5.2 percent vs. –0.3 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 2024, urban facilities averaged roughly 11,000 treatments while rural facilities averaged nearly 7,700 treatments (data not shown). Higher-volume facilities had lower cost per treatment (Figure 5-2).

Although some rural facilities in 2024 benefited from the ESRD PPS's 23.9 percent LVPA (for those furnishing fewer than 4,000 treatments) 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). Beginning in 2025, dialysis facilities

furnishing fewer than 3,000 treatments receive a 28.9 percent upward payment adjustment, and those furnishing between 3,000 and 3,999 treatments receive an 18.3 percent upward payment adjustment per the two-tiered LVPA policy finalized in the 2025 ESRD PPS final rule. CMS contends that this modification better targets payment increases to facilities with higher costs (Centers for Medicare & Medicaid Services 2024c). 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 2020b). We expect that this recommendation would increase the aggregate Medicare margin for isolated, low-volume facilities located in rural areas.[39]

Projecting payments and costs for 2026

To estimate the projected 2026 margin, the Commission considers providers' cost growth between 2019 and 2024 and policy changes affecting payments in 2025 and 2026. These factors include:

- statutory updates to the dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) of 2.2 percent in 2025 and 2.1 percent in 2026; and
- reductions in payments of 0.37 percent in 2025 and 0.23 percent in 2026 due to the ESRD Quality Incentive Program.

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

- add-on payments in 2025 and 2026 for new ESRD drugs (including Vafseo (for treatment of anemia), Korsuva (for treatment of pruritus), and DefenCath (which reduces incidence of catheter-related bloodstream infections)) and in 2025, for at least two years, for phosphate binders; and
- both LDOs' productivity efficiencies in 2025; for example, one LDO reduced ESRD drug costs by switching its patients to epoetin beta, and both LDOs have been maximizing their capacity utilization by merging and closing facilities and promoting home dialysis.

We project that the FFS Medicare margin will decline from 4.5 percent in 2024 to 4 percent in 2026, in aggregate.

How should FFS Medicare payments change in 2027?

Most payment-adequacy indicators—beneficiary access to care, quality of care, provider access to capital—for outpatient dialysis facilities are adequate, and the projected FFS Medicare margin for 2026 is 4 percent. Under current law, Medicare's base payment rate under the ESRD PPS will be increased in 2027 based on the forecasted increase in the ESRD market basket less a forecasted increase in productivity. CMS will revise its estimates before setting rates for 2027; however, we note that CMS currently forecasts a 1.6 percent increase in the base payment rate. The final 2027 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 to the base payment rate, Medicare pays dialysis facilities for qualifying new drugs that treat a condition included in 1 of 11 functional categories of products that are covered under the ESRD PPS TDAPA and post-TDAPA for a five-year period. The new ESRD drugs paid under such add-on payment policies may increase FFS Medicare payments relative to facilities' costs. Specifically, CMS does not reconcile the cost and utilization of the new drug paid under an add-on payment in 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. Essentially, the current add-on payment policies for ESRD drugs in an existing ESRD functional category create a second (duplicative) payment for new ESRD drugs that treat the same clinical condition as drugs already included in the payment bundle.

The TDAPA for phosphate binders that began in 2025 may increase FFS Medicare payments relative to facilities' costs, like the TDAPA for calcimimetics did

TABLE 5–6

In 2024, the FFS Medicare margin of freestanding dialysis facilities varied by treatment volume

Provider type	FFS Medicare margin	Share of freestanding dialysis facilities	Share of freestanding dialysis facility treatments
All	4.5%	100%	100%
Urban	5.2	85	89
Rural	–0.3	15	11
Treatment volume (quintile)			
Lowest	–11.6	20	8
Second	–5.1	20	13
Third	1.9	20	18
Fourth	6.0	20	24
Highest	11.3	20	38

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 from the Dialysis Compare database.

between 2018 and 2020 (Figure 5-3, p. 173). Although some stakeholders have raised concerns that paying for phosphate binders under the ESRD PPS may have a negative effect on providers' financial performance, three of the five largest dialysis organizations operate their own pharmacies, which gives them advantages such as managing costs and maintaining greater control of and more complete information on their patients' prescriptions (Government Accountability Office 2023). Furthermore, both LDOs reported a positive impact from furnishing phosphate binders (Fresenius Medical Care 2025a). Indeed, one of the LDOs reported that revenue per treatment for phosphate binders exceeded their cost per treatment ($10 vs. $8, respectively) (DaVita 2025b).

There is some evidence that dialysis facilities have generally become more efficient under the ESRD PPS, as measured by declining use of most injectable ESRD 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: increased demand for home dialysis, the excess mortality during the coronavirus pandemic, and the slower growth of ESRD incidence over the past decade.

RECOMMENDATION 5

For calendar year 2027, the Congress should eliminate the update to the 2026 Medicare base payment rate for outpatient dialysis services.

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 ESRD drugs under the ESRD PPS. Indicators of quality of care are mixed. The FFS Medicare margin was 4.5 percent in 2024 and is projected to be 4 percent in 2026. We do not yet know the effect of Medicare's add-on payments for new renal dialysis drugs and phosphate binders on facilities' financial performance in 2025 and 2026, but our prior analysis showed that add-on payments for calcimimetics between 2018 and 2020 contributed to a substantial increase in facilities' FFS Medicare

margin during that period. The two LDOs—companies that account for three-quarters of dialysis facilities—recently made optimistic statements about their dialysis business, including productivity gains in 2025. Low-volume dialysis facilities, which tend to have higher costs due to fewer economies of scale, may be helped by increased payments under the ESRD PPS's refined low-volume payment adjustment beginning in 2025.

IMPLICATIONS 5

Spending

- Current law is expected to increase the base payment rate by 1.6 percent in 2027. This recommendation would lower spending relative to current law by between $50 million and $250 million over one year and between $1 billion and $5 billion over five years.

Beneficiary and provider

- We expect beneficiaries on dialysis to continue to have good access to outpatient dialysis 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 In this chapter, the term "drugs" refers to both drugs and biologics. The term "biologics" refers to biological products.

3 Individuals with ESRD have been entitled to Medicare Part A and Part B benefits since the 1972 amendments to the Social Security Act that extended Medicare benefits to this population (Social Security Administration 2024). For individuals with ESRD to qualify for Medicare, including those under age 65, they must be fully or currently insured under the Social Security or Railroad Retirement program or be the spouse or dependent child of an eligible beneficiary. When a beneficiary enrolls in Medicare based on ESRD, Medicare coverage usually begins on the first day of the fourth month of dialysis treatment in a dialysis facility. The 1972 law included a three-month waiting period to address financing issues (Institute of Medicine Committee to Study Decision Making 1991). Per the ESRD Program Amendment of 1978 (P.L. 95-292), Medicare coverage can start as early as the first month of dialysis if the beneficiary takes part in a home dialysis training program (Centers for Medicare & Medicaid Services 2025a). According to Eggers (1984), the 1978 law included this waiver to promote home dialysis and to increase the cost-efficiency of the ESRD program (Eggers 1984).

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, and whether the beneficiary receives dialysis in a facility or at home.

5 In 2021, private equity firm Nautic Partners and its portfolio company, Innovative Renal Care, acquired American Renal Associates (American Renal Associates 2021).

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

7 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; and drugs approved that changed from prescription to over-the-counter availability. CMS identifies these drugs using the application classification code for new drugs, which the FDA assigns to a given drug.

8 CMS calculates the TDAPA and post-TDAPA payments differently. The TDAPA payment for new, qualifying drugs is based on the number of units of the new drug furnished to the beneficiary multiplied by average sales price plus 0 percent. CMS pays a post-TDAPA on all ESRD PPS claims; the payment rate is case-mix adjusted and set at 65 percent of the estimated expenditure levels for the given ESRD drug in the prior year.

9 The receipt of post-TDAPA add-on payment adjustments is conditional on continued receipt of the latest full calendar quarter of average sales price data.

10 In the 2026 ESRD PPS final rule, CMS finalized the proposed rule to not pay a post-TDAPA for Jesduvroq after the end of the product's TDAPA period on September 30, 2025. The manufacturer of Jesduvroq withdrew the product from the market for reasons unrelated to safety or effectiveness (Food and Drug Administration 2024a).

11 Unlike for new ESRD drugs paid under a TDAPA, a substantial-clinical-improvement standard is used to determine eligibility for a TPNIES add-on. According to CMS, the two-year TDAPA for new ESRD drugs in an existing functional category does not include a standard for substantial clinical improvement because "allowing all new drugs to be eligible for TDAPA will provide an opportunity for the new drugs to compete with other similar drugs in the market which could mean lower prices for all drugs. We believe drug manufacturers understand that if they are to compete with drugs currently in the ESRD–PPS bundle, they need to not only be better, but they also must come in at a lower price in order to continue to be utilized by facilities in the post-TDAPA period. The 2-year TDAPA period gives the innovative product an opportunity to demonstrate its clinical value and financial worth, while buffering the risk to both the manufacturer and the facility. If the facility finds the product sufficiently worthy of use among its patients, then the manufacturer has an incentive to keep the price lower than the drug it is replacing that is currently in the bundle. In addition, the effectiveness of drugs can depend on age, gender, race, genetic predisposition and comorbidities. Innovation can provide options for those that do not respond to a certain preferred treatment regimen the same way the majority

of patients respond" (Centers for Medicare & Medicaid Services 2018). 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" in our *Payment Basics* series, available at https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_25_dialysis_FINAL_SEC.pdf).

12 The payment rate reflects (1) the base rate adjusted for each beneficiary's and facility's characteristics, (2) add-on payments for qualifying technologies, (3) a training add-on payment for home and self-dialysis modalities, (4) a transitional pediatric add-on payment, (5) payment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, (6) the ESRD quality incentive adjustment, (7) payment adjustments due to the ESRD Treatment Choices Model, and (7) the Medicare sequester.

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

14 In the 2026 ESRD PPS final rule, CMS terminated the ETC Model as of December 31, 2025. According to CMS, the early termination of this mandatory model stems from it having no impact on home dialysis, waitlisting for kidney transplants, and living donor transplant rates in the first three years of the model (Centers for Medicare & Medicaid Services 2025b).

15 Some portion of the decline in 2021 in the number of FFS beneficiaries on dialysis 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 Medicare pays for up to three dialysis treatments per week, though exceptions can be made with medical justification (Centers for Medicare & Medicaid Services 2023b).

17 ESAs include epoetin alfa reference, epoetin alfa biosimilar, epoetin beta, and darbepoetin. Iron agents include iron sucrose and sodium ferric gluconate. Vitamin D agents include calcitriol, doxercalciferol, and paricalcitol. Calcimimetics include cinacalcet and etelcalcetide. Other drugs include daptomycin, vancomycin, alteplase, and levocarnitine.

18 To measure changes in the use of most 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 2024 average ASP. However, because 2024 ASP data were not available for cinacalcet, we used CMS's TDAPA payment limit for the fourth quarter of 2020 and updated it to 2024 dollars using pharmaceutical Producer Price Indexes. Also, because 2024 ASP data were not available for calcitriol, we used CMS's published 2023 ASP data and updated them to 2024 dollars using pharmaceutical Producer Price Indexes. By holding the price constant, we account for the different billing units assigned to a given drug.

19 Our analyses of CMS enrollment and supplemental coverage data show that in 2024, approximately 45 percent of FFS beneficiaries on dialysis without cost sharing covered by Medicaid had no supplemental coverage (that is, coverage from other sources, such as Medigap or employer-sponsored health plans) compared with 25 percent of all other FFS beneficiaries without cost sharing covered by Medicaid.

20 Once beneficiaries with ESRD turn 65, for a six-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: 36 states require insurers to offer at least one Medigap plan to beneficiaries under age 65 (American Kidney Fund 2024, Freed et al. 2024).

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

22 For example, blood transfusion use, which initially increased under the PPS, has declined since 2013 (Centers for Medicare & Medicaid Services 2023a).

23 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.

24 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.

25 According to CMS, the monthly share of beneficiaries going to the ED varies based on beneficiaries' age, race, and eligibility for Medicaid. In 2023, the share of beneficiaries going to the ED is higher among (1) older beneficiaries compared to younger beneficiaries, (2) White, Black, or Hispanic beneficiaries compared to Asian beneficiaries; and (3) dually eligible beneficiaries compared to non-dual-eligible beneficiaries (Centers for Medicare & Medicaid Services 2023a).

26 CMS cites "survey fatigue" and declining survey response rates as the motivation for reducing the length of the ICH CAHPS, and notes that the decision to remove measures related to nephrologists was based on feedback that "(1) patients are not always able to differentiate a kidney doctor from other dialysis center staff when answering questions, (2) nephrologists are often separate from the facility and may have patients in multiple facilities, and (3) there is nothing actionable that a facility can do based on the nephrologists' communication and caring scores or nephrologists' ratings" (Centers for Medicare & Medicaid Services 2025b).

27 Lin and colleagues analyzed data for individuals starting dialysis between 2006 and 2013 across all insurance types (Lin et al. 2017). The authors concluded that (1) the bundling implemented in the ESRD PPS was associated with substantial increases in home dialysis, which were identical for both Medicare and non-Medicare patients; and (2) the increase in home dialysis use among patients with other insurance types (i.e., not enrolled in FFS Medicare) indicates spillover effects of the ESRD PPS.

28 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 https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_medpac_ch6_sec.pdf).

29 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.

30 In the 10 years since the implementation of the kidney-allocation system by the United Network for Organ Sharing, between 2014 and 2024, the share of transplants for Black and Hispanic patients rose from 25 percent to 30 percent and 16 percent to 20 percent, respectively.

31 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 2023, Medicare spending for outpatient dialysis services for FFS beneficiaries with AKI was $75 million, a 4 percent increase compared with 2022. 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.

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

33 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 the inclusion of oral-only ESRD drugs in the ESRD PPS bundled payment until January 1, 2025.

34 In the 2025 ESRD PPS final rule, CMS said that the agency may reevaluate the amount of the monthly fixed-rate addition in future rulemaking, if appropriate.

35 The FFS Medicare margin includes Medicare's payments and providers' allowable costs for qualifying ESRD drugs and items paid under the TDAPA, post-TDAPA, and TPNIES.

36 Add-on payments for calcimimetics between 2018 and 2020 contributed to a substantial increase in facilities' FFS Medicare margin during that period.

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

38 The sharp increase in the 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).

39 According to CMS, Section 1881(b)(14)(D)(iii) of the Social Security Act—which requires that the LVPA reflect the extent to which low-volume facilities incur higher costs relative to other facilities—limits the agency's ability to address the geographic isolation of a dialysis facility through the LVPA because its analysis found that low-volume facility costs do not vary by geographic isolation (Centers for Medicare & Medicaid Services 2024c).

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