CHAPTER 5

Outpatient dialysis services

RECOMMENDATION

5 For calendar year 2026, the Congress should update the 2025 Medicare base payment rate for outpatient dialysis services by the amount determined under current law.

COMMISSIONER VOTES: YES 15 • NO 0 • NOT VOTING 2 • 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 2023, about 262,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 7,700 dialysis facilities. In 2023, the FFS Medicare program and its beneficiaries spent $8.1 billion for outpatient dialysis services.

Assessment of payment adequacy

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

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

- ***Capacity and supply of providers*—**The capacity of dialysis facilities appears to exceed demand. Between 2022 and 2023, the number of in-center treatment stations was steady while the number of Medicare beneficiaries on dialysis enrolled in either FFS Medicare or Medicare Advantage (MA) declined, likely due to the excess mortality experienced by the population with ESRD during the coronavirus pandemic. In addition, over the last decade, the adjusted rate of

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new ESRD cases has declined. Between 2022 and 2023, the share of total treatments furnished by freestanding dialysis facilities in the home continued to increase.

- ***Volume of services*—**The 11 percent decline in FFS treatments between 2022 and 2023 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 in 2021—the first year of the statutory change—and by about 12 percent annually between 2021 and 2023. 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.
- ***FFS Medicare marginal profit*—**An estimated FFS Medicare marginal profit of 17 percent in 2023 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries.

***Quality of care*—**Rates of all-cause hospitalization, emergency department use, and mortality among FFS beneficiaries on dialysis held relatively steady between 2022 and 2023, as did measures of their experience receiving in-center hemodialysis. The share of 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. Under the ESRD prospective payment system (PPS), the two largest dialysis organizations have grown through acquisitions of and mergers with midsize dialysis organizations. In 2023 and 2024, facility closures and consolidations by each of the two largest dialysis organizations aimed to reduce overcapacity related to the increasing use of home dialysis and the decline in patient census in some markets.

***FFS Medicare payments and providers' costs*—**Between 2022 and 2023, FFS Medicare payment per treatment in freestanding dialysis facilities (which provide the vast majority of FFS dialysis treatments) grew by 3 percent while cost per treatment rose by 2 percent. In 2023, a decline in cost growth was observed across most cost categories, including capital, ESRD drugs, and labor.

Consequently, the FFS Medicare margin rose from −1.1 percent in 2022 to −0.2 percent in 2023. We project a 2025 FFS Medicare margin of 0 percent. This projection does not account for the add-on payments for new ESRD drugs and phosphate binders in 2024 and 2025, which may increase FFS Medicare payments relative to facilities' costs.

How should FFS Medicare payments change in 2026?

Under current law, the FFS Medicare base payment rate for dialysis services is projected to increase by 1.7 percent in 2026. Though the FFS Medicare margin is low, other indicators of payment adequacy are generally positive. Thus, the Commission recommends that, for calendar year 2026, the Congress update the 2025 base payment rate for outpatient dialysis services 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 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. ■

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 patients with ESRD 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 that result from the loss of kidney function.

In 2023, roughly half of Medicare's beneficiaries with ESRD on dialysis were covered by fee-for-service (FFS) Medicare and half were enrolled in Medicare Advantage (MA).

- In January 2023, roughly 216,400 beneficiaries on dialysis were covered under FFS Medicare while nearly 211,900 beneficiaries on dialysis were enrolled in MA.
- By December 2023, the number of FFS beneficiaries on dialysis declined to 199,800 while the number of MA beneficiaries on dialysis increased to 220,300.

About 7,700 dialysis facilities provided outpatient dialysis services to FFS beneficiaries in 2023. The dialysis sector is highly consolidated, with two large dialysis organizations (LDOs)—Fresenius Medical Care and DaVita—dominating the industry. In 2023, these LDOs accounted for three-quarters of facilities and FFS Medicare treatments. Moreover, in 2023, the five largest dialysis organizations accounted for roughly 87 percent of facilities and 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.[1,2] 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 2023, the FFS Medicare program and its beneficiaries spent $8.1 billion for outpatient dialysis services. This total includes nearly $26 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 2022 (the most recent year of data available), Part D gross spending for ESRD oral-only drugs that have not yet been included in the PPS—several phosphate binders—totaled nearly $0.7 billion for FFS beneficiaries on dialysis.

Characteristics of fee-for-service beneficiaries on dialysis, 2023

Compared with other FFS Medicare beneficiaries, FFS beneficiaries on dialysis are disproportionately younger, male, and Black or Hispanic (Table 5-1). In 2023, 72 percent of FFS beneficiaries on dialysis were under 75 years old (with 43 percent under 65 years old), 58 percent were male, 29 percent were Black, and 15 percent were Hispanic. By comparison, among other FFS Medicare beneficiaries, 57 percent were under 75 years old (with 10 percent 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. 79 percent).

FFS beneficiaries on dialysis are more likely than all other FFS beneficiaries to have full Medicaid benefits (38 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 (61 percent vs. 23 percent) (data not shown).

Over the last decade, the adjusted rate of new ESRD cases, or incidence rate, in the U.S. population (which includes patients of all types of health coverage who initiate dialysis or receive a kidney transplant) has declined. Between 2012 and 2022 (the most recent year of data available), the adjusted incidence rate decreased by 1 percent per year, from 425 per million people to 381 per million people (United States Renal Data System 2024b). This decline may be attributable to changes such as better management of ESRD-related comorbidities but also to the excess mortality during the coronavirus pandemic.[3] We estimate that nearly 65,000 FFS beneficiaries began dialysis in 2023 (a decline of 2 percent compared with 2022).

The share of beneficiaries on dialysis enrolling in Medicare Advantage plans has increased rapidly since 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: Beneficiaries could enroll in a plan specifically designed for ESRD enrollees, and those beneficiaries who had enrolled in MA before being diagnosed with ESRD could stay in the plan after they were diagnosed. Beginning in January 2021, the 21st Century Cures Act permitted beneficiaries on dialysis to enroll in MA plans. As a result of this statutory change, the share of beneficiaries on dialysis enrolled in MA plans increased rapidly from 25 percent in January 2020 to 52 percent by December 2023 (Figure 5-1, p. 154).

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 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 is access to the additional benefits that plans provide versus a broader choice of providers participating in FFS. 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 choose to include fewer dialysis facilities in their network, travel time for some MA beneficiaries to a dialysis facility could be affected. Researchers show that increased travel time to a facility increases the number of missed treatments and is associated with worse outcomes for patients, and difficulty with transportation more generally is also associated with missed dialysis treatments and increased morbidity and mortality in patients with ESRD (Moist et al. 2008). (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).)

TABLE 5–1

FFS beneficiaries on dialysis are disproportionately young, male, Black, and Hispanic compared with other FFS beneficiaries, 2023

	Share of FFS beneficiaries:	
	Beneficiaries on dialysis	**Other beneficiaries**
Age		
Under 45 years	10%	3%
45–64 years	33	7
65–74 years	29	47
75–84 years	21	31
85+ years	7	12
Sex		
Male	58	45
Female	42	55
Race		
White	43	80
Black	29	7
Hispanic	15	5
Asian	6	3
All others	7	4
Residence, by type of county		
Urban	84	79
Micropolitan	9	11
Rural, adjacent to urban	4	5
Rural, not adjacent to urban	2	4

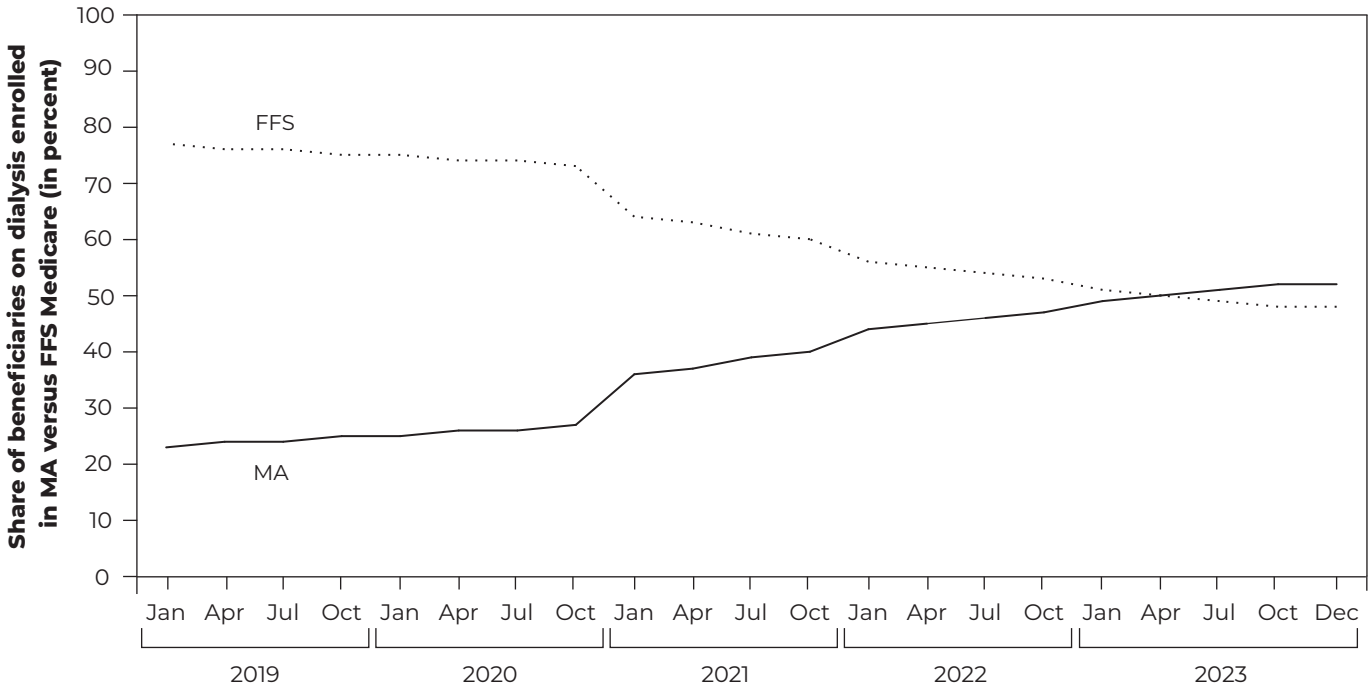
Note: FFS (fee-for-service). "Other beneficiaries" excludes beneficiaries on dialysis and those who have received a kidney transplant. "Residence" reflects the beneficiary's county of residence in one of four categories (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based 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, 2023.

Given the magnitude of total health care expenses incurred annually by beneficiaries on dialysis (for dialysis and other outpatient and inpatient services and Part D drugs—averaging nearly $102,000 in 2022, with beneficiary out-of-pocket liability averaging nearly $14,000), these beneficiaries face significant out-of-pocket expenses when they are enrolled in FFS 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 $8,850 for in-network services in 2024 (and $13,300 for in- and out-of-network services covered by preferred provider organizations (PPOs)), but most plans elect to offer a lower MOOP limit: In 2023, about three-quarters of conventional MA plans had MOOPs lower than the mandatory limit (Medicare Payment Advisory Commission 2023). Beneficiaries who have full Medicaid coverage, as well as qualified Medicare beneficiaries (QMBs) with partial dual eligibility, have their cost sharing covered by Medicaid but may

FIGURE 5–1

The share of beneficiaries on dialysis enrolling in MA plans continued to increase between 2021 and 2023



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

Source: Data compiled by MedPAC from CMS enrollment data and risk-score files, 2019–2023.

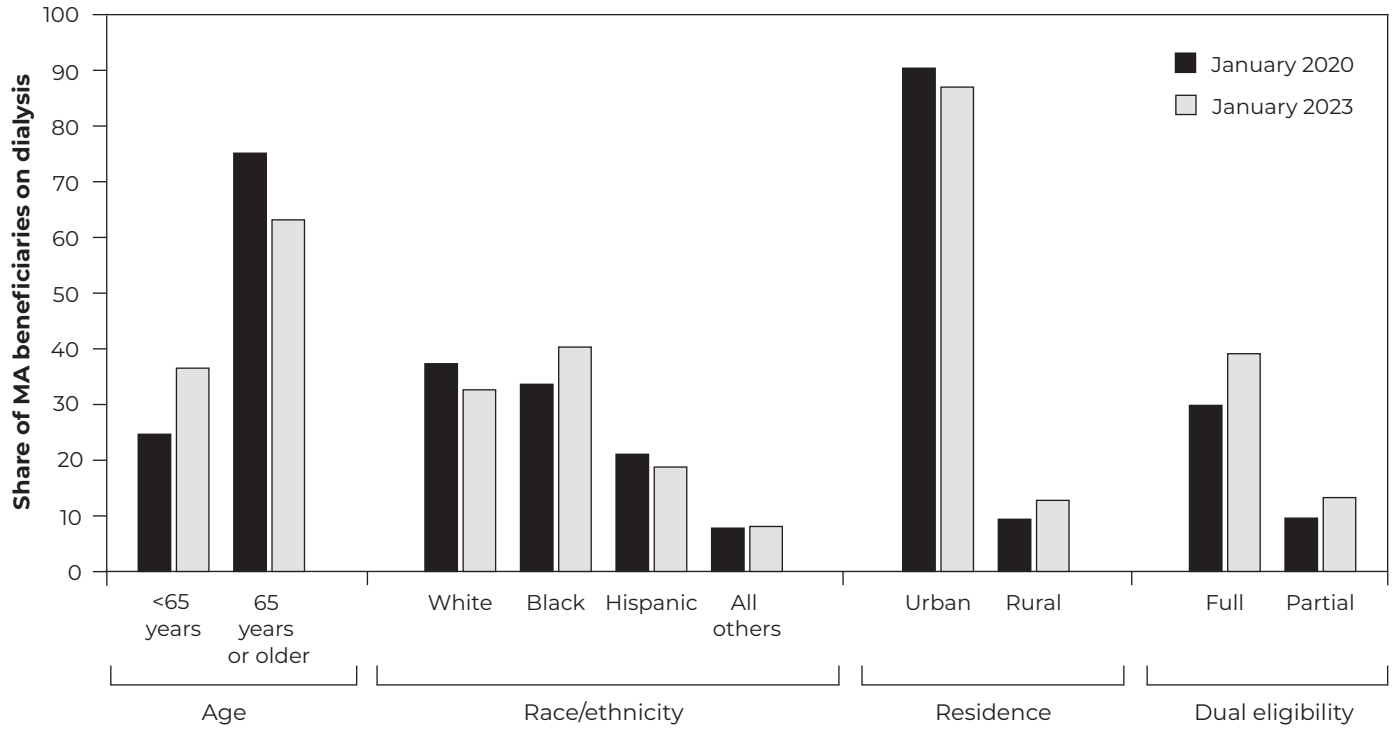
still find it desirable to enroll in an MA plan for the supplemental benefits offered (see text box on MA dialysis beneficiaries switching between plans and coverage options, pp. 158–159).

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 (32 percent vs. 49 percent in 2023)[4] 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.[5]
- *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.[6]

Changes in the characteristics of MA beneficiaries on dialysis, 2020 to 2023 Before the 21st Century Cures Act, beneficiaries with ESRD under age 65 and not already enrolled in MA before the onset of ESRD were

FIGURE 5–2 **The composition of MA beneficiaries on dialysis changed between 2020 and 2023**



Note: MA (Medicare Advantage). Beneficiaries on dialysis were identified using the risk-score file, and fee-for-service Medicare versus MA enrollment was identified using CMS enrollment data. "Residence" reflects the beneficiary's county of residence in one of two categories, urban or rural (the latter category includes micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the Urban Influence Codes.

Source: Data compiled by MedPAC from CMS enrollment data, risk-score file, U.S. Census delineation file, CMS–2728, 2020 and 2023.

not eligible to enroll in most MA plans. Since the removal of enrollment barriers in 2021, a greater share of MA beneficiaries with ESRD in 2023 are under age 65 (a 12 percentage point increase since 2020) (Figure 5-2). A lower share of MA beneficiaries with ESRD in 2023 are new to dialysis in 2023 (less than one in five) than in 2020 (about one in four) (data not shown).

Between 2020 and 2023, the composition of MA beneficiaries on dialysis also changed by race and ethnicity and dual eligibility. A greater share of MA beneficiaries on dialysis in 2023 than in 2020 were Black (a 7 percentage point increase) and dually eligible for Medicare and Medicaid (a 9 percentage point and 4 percentage point increase for full- and partial-benefit dually eligible beneficiaries, respectively). These enrollment trends are consistent with MA growth over time among beneficiaries without ESRD (Medicare Payment Advisory Commission 2024, Meyers et al. 2021, Xu et al. 2023). There was a corresponding 17 percentage point increase in the share of MA beneficiaries on dialysis enrolled in dual-eligible special needs plans, from 17 percent in 2020 to 35 percent in 2023.

Characteristics of MA beneficiaries on dialysis, 2023

By 2023, a greater share of MA beneficiaries than FFS beneficiaries on dialysis were older, Black, partially dually eligible, and residing in urban areas (Table 5-2).

TABLE 5–2

A greater share of MA beneficiaries than FFS beneficiaries on dialysis are over age 65, Black, dually eligible for Medicare and Medicaid, and urban residents, 2023

	Share of beneficiaries on dialysis:	
	FFS	**MA**
Total	216,400	211,900
Age		
Under 45 years	10%	6%
45–64 years	34	31
65–74 years	28	33
75–84 years	21	24
85+ years	7	7
Sex		
Male	59	56
Female	41	44
Race		
White	43	33
Black	30	40
Hispanic	15	19
Asian	6	5
All others	6	3
Residence, by type of county		
Urban	83	87
Rural	16	13
Dual eligibilty		
Fully dually eligible for Medicaid	38	39
Partially dually eligible for Medicaid	7	13
Not dually eligible for Medicaid	56	48
Part D enrollment		
Yes	73	98
No	27	2
New to dialysis vs. existing dialysis		
New	18	18
LDO	73	74
Non-LDO	27	26
Existing	83	82

Note: MA (Medicare Advantage), FFS (fee-for-service), LDO (large dialysis organization (DaVita and Fresenius Medical Care)). Beneficiaries on dialysis were identified using the risk-score file, and FFS versus MA enrollment was identified using CMS enrollment data. "Residence" reflects the beneficiary's county of residence in one of two categories, urban or rural (the latter category includes micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the Urban Influence Codes. Data as of January 2023. Components may not sum to 100 percent due to rounding.

Source: Data compiled by MedPAC from CMS enrollment data, risk-score file, U.S. Census delineation file, CMS–2728, 2023.

In 2023, 64 percent of MA beneficiaries on dialysis were 65 years or older (with 31 percent being 75 years or older), 40 percent were Black, 13 percent had partial dual eligibility, and 87 percent resided in urban areas. By comparison, among FFS beneficiaries on dialysis, 56 percent were 65 years or older (with 28 percent being 75 years or older), 30 percent were Black, 7 percent had partial dual eligibility, and 83 percent resided in urban areas. Among MA beneficiaries on dialysis, 58 percent were covered by the top three MA parent organizations in 2023 (UnitedHealth Group Inc., Humana Inc., and CVS Health Corporation; data not shown).

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.[7] 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 American Renal Associates and U.S. Renal Care, have established joint ventures with physicians. 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 (see the Commission's March 2021 report, Chapter 12, on MA plan payments to dialysis facilities for services provided to MA beneficiaries on dialysis) (Medicare Payment Advisory Commission 2021). 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 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).[8] Medicare pays facilities furnishing 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.[9] The two-year transitional drug add-on payment adjustment (TDAPA) for Korsuva (an antipruritic) ended March 31, 2024, while the TDAPA for Jesduvroq (used to treat anemia) will conclude on September 30, 2025. Under current regulations, both drugs will be paid under a post-TDAPA for three years at the end of each drug's TDAPA period.[10] The two-year transitional payment adjustment for new and innovative equipment and supplies (TPNIES) for the Tablo Hemodialysis System concluded in December 2023.[11]

Are FFS Medicare payments adequate in 2025?

To address whether payments for 2025 are adequate to cover the costs to efficiently provide care and to determine how much payments should change in the update year (2026), 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

Switching between plans and coverage among beneficiaries on dialysis

Each year during the annual open enrollment period between October 15 and December 7, Medicare beneficiaries may switch between fee-for-service (FFS) and Medicare Advantage (MA) coverage or between MA plans for beneficiaries who are already in MA. MA enrollees have an additional window to make changes during the MA open enrollment period, January 1 through March 31. Those beneficiaries who are dually eligible for Medicare and Medicaid may switch their plans or coverage quarterly through the first three quarters of the year. All beneficiaries may qualify to switch plans or their coverage during special enrollment periods (SEPs) throughout the year. As more beneficiaries on dialysis continue to enroll in MA, it is important to monitor the prevalence of switching as a measure of their experience in the MA program.

Between-year switching

We examined switching behavior among beneficiaries with ESRD on dialysis by comparing beneficiaries' coverage (FFS vs. MA) and plan enrollment between December and January each year. Following the 21st Century Cures Act, there was a surge in beneficiaries switching from FFS to MA between December 2020 and January 2021 (about 37,000 beneficiaries, or 9 percent of all beneficiaries on dialysis). Fewer beneficiaries switched from FFS to MA in subsequent years (about 15,600, or 4 percent, between December 2021 and January 2022 and 13,000, or 3 percent, between December 2022 and January 2023). Each year between 2020 and 2023, fewer than 2,000 (or 0.5 percent) MA beneficiaries on dialysis disenrolled from MA to enroll in FFS (Figure 5-3). By contrast, between December 2022 and January 2023, approximately 2 percent of MA beneficiaries without ESRD switched from FFS to MA, and another 0.3 percent disenrolled from MA to FFS. The number of beneficiaries on dialysis staying in MA but switching plans between years grew over time, from about 11,000 beneficiaries, or 3 percent, between December 2020 and January 2021 to about 21,500 beneficiaries, or 5 percent, between December 2022 and January 2023. A similar share of MA beneficiaries without ESRD switched between MA plans between December 2022 and January 2023 (5 percent).

Midyear switching

Beneficiaries may switch their MA plans midyear for any number of reasons, including various life events that qualify them for SEPs, dissatisfaction with their current plan, or in response to marketing by MA plans. Switching MA plans midyear, however, may impact these beneficiaries' cost-sharing liabilities because switching to a plan offered by a different parent organization or to a different plan type within the same parent organization will reset beneficiaries' contributions toward the maximum out-of-pocket (MOOP) amount (Centers for Medicare & Medicaid Services 2016). Whether and how many MA beneficiaries are aware of the financial repercussions of their plan switch is unknown.

Resetting beneficiaries' contributions toward their MOOP will increase the cost-sharing liabilities for beneficiaries without Medicaid benefits, as well as those with partial dual eligibility (minus qualified Medicare beneficiaries (QMBs) with partial dual eligibility). In addition to increasing the financial burden on beneficiaries, MOOP resets may also result in greater unpaid patient balances for dialysis facilities; without a MOOP reset, MA plans would assume responsibility sooner for the 20 percent coinsurance for dialysis treatments once the MOOP is reached. In 2023, approximately 9,000 (or 7 percent) of non-dual-eligible MA beneficiaries on dialysis and 3,000 (or 17 percent) of partial dual-eligible MA beneficiaries on dialysis (excluding partially dual-eligible QMBs) made a midyear switch that would have resulted in a MOOP-contribution reset. Among MA beneficiaries without ESRD, 4 percent of non-dual-eligible beneficiaries and 16 percent of partial dual-eligible beneficiaries (excluding partially dual-eligible QMBs) made a midyear switch that would have resulted in a MOOP-contribution reset.

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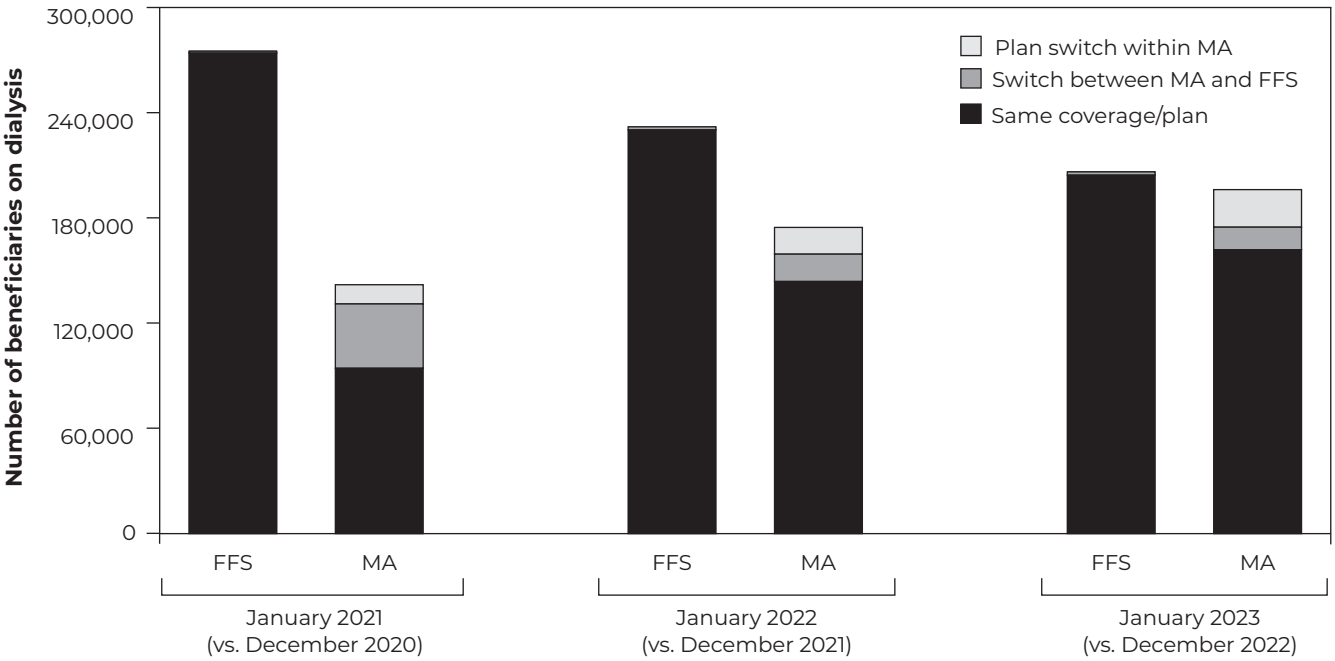
Switching between plans and coverage among beneficiaries on dialysis (cont.)

FIGURE 5–3

A growing share of MA beneficiaries on dialysis are switching plans between years



Note: MA (Medicare Advantage), FFS (fee-for-service). The bars represent enrollment changes between December of the prior year and January of the labeled year. Only beneficiaries enrolled in Medicare and on dialysis for the two consecutive months (December–January) are included in this figure. For example, the 2023 bars represent enrollment changes between December 2022 and January 2023. "Same coverage/plan" represents beneficiaries who are enrolled in FFS or MA both years. "Switch between MA and FFS" represents beneficiaries who switch enrollment between MA and FFS in December of the prior year to January of the next year. "Plan switch within MA" represents beneficiaries who are enrolled in MA both years but in different MA plans. For the MA bars, switchers are people who were in FFS in December of the previous year. For the FFS bars, switchers are people who were in MA in December of the previous year.

Source: Data compiled by MedPAC from CMS enrollment data and risk-score file, 2020–2023.

Beneficiaries with full dual eligibility and QMBs with partial dual eligibility have their cost sharing paid for by Medicaid and will not experience the impact of such a MOOP-contribution reset. In 2023, about 17,500 (or 15 percent) of dually eligible MA beneficiaries on dialysis who have their cost sharing paid for by Medicaid (i.e., all those with full Medicaid benefits plus partially dual-eligible QMBs) made a midyear switch that would have reset their MOOP contribution. A similar share (14 percent) of dually eligible MA beneficiaries without ESRD who have their cost sharing paid for by Medicaid made a midyear switch that would have reset their MOOP contribution. ■

are positive. The FFS Medicare margin rose from −1.1 percent in 2022 to −0.2 percent in 2023 because providers' cost per treatment grew more slowly in 2023 than in 2022 and because payment per treatment increased more than cost per treatment in 2023.

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 beneficiaries on dialysis under the PPS—shows that beneficiaries' access to care remains generally favorable.

Capacity has exceeded demand from patients on dialysis across all insurance types

In 2023, there were 7,714 dialysis facilities nationwide. FFS Medicare accounted for about 37 percent of all treatments furnished by freestanding providers.[12] Between 2019 and 2022, growth in the number of dialysis facilities and in-center treatment stations exceeded growth in the number of patients on dialysis, across all insurance types. During that period, the number of facilities and their capacity to provide care—as measured by dialysis treatment stations—both grew by 1 percent annually (Table 5-3). By comparison, the number of patients on dialysis of all types of health coverage declined by nearly 1 percent per year between 2019 and 2022 (most current year of data available) (United States Renal Data System 2024a).

The number of facilities' in-center treatment stations grew more slowly between 2022 and 2023 compared with the annual growth from 2019 through 2022 (0.3 percent per year vs. 1.0 percent per year) but exceeded growth in the number of Medicare beneficiaries on dialysis. Between 2022 and 2023, the number of FFS and MA enrollees on dialysis declined by 2 percent. The slower growth of in-center capacity and the number of facilities from 2022 to 2023 compared with 2019 through 2022 may have been in response to declining demand for ESRD services. Between 2022 and 2023, total dialysis treatments (across all payers) declined by 1 percent and total in-center treatments furnished by freestanding dialysis facilities declined by 2 percent. The decline in demand may be attributable to factors such as the following:

- Excess mortality in the population of patients with ESRD during the coronavirus pandemic. One of the LDOs reported in 2023 that the excess mortality negatively affected same-market treatment growth (Fresenius Medical Care 2023d).
- The decline in the incidence of ESRD during the past decade (by 1 percent per year between 2012 and 2022) (United States Renal Data System 2024b).
- The increase in the use of home dialysis, which has reduced the demand for in-facility treatments. Based on data from Medicare claims, 56 percent of facilities offered home dialysis in 2023, up from 53 percent in 2022. In addition, the CMS Innovation Center's mandatory ESRD Treatment Choices (ETC) Model rewards dialysis facilities and clinicians who are part of the model for increasing home dialysis use and kidney transplantation among adult beneficiaries on dialysis and penalizes facilities and clinicians who are not.

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. In 2022 and 2023, the total number of facilities operated by the two LDOs declined in each year by 2 percent (DaVita 2024a, DaVita 2022b, Fresenius Medical Care 2024b). Closing or merging facilities improves 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 2023, freestanding facilities furnished 96 percent of FFS treatments, and for-profit facilities furnished 90 percent (Table 5-3). Between 2022 and 2023, capacity (as measured by the number of in-center stations) grew at both freestanding and hospital-based facilities by 0.3 percent, and at for-profit facilities by roughly 1 percent, while capacity at nonprofit facilities fell by roughly 5 percent.

The capacity of facilities in urban and rural areas in 2023 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 2022 and 2023, capacity at urban facilities grew by 0.4 percent while capacity at all rural facilities declined by 1 percent (data not shown). In June 2020, the Commission recommended that the Secretary replace the ESRD PPS's low-volume payment adjustment (LVPA) and rural adjustment with a single payment adjustment—a low-volume

TABLE 5–3

Low growth in the capacity of freestanding and for-profit dialysis organizations between 2022 and 2023

	2023				Average annual percent change			
					2019–2022		2022–2023	
	Total number of FFS treatments	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	27.4 million	7,714	138,542	18	1%	1%	–2%	0.3%
	Share of total							
Freestanding	96%	95%	96%	18	1	1	–2	0.3
Hospital based	4	5	4	14	–3	–3	–2	0.3
Urban	86	84	87	19	1	1	–2	0.4
Micropolitan	10	10	9	16	0	0	–2	0.3
Rural, adjacent to urban	2	4	3	14	–2	–1	–5	–3
Rural, not adjacent to urban	1	2	1	12	–1	–1	–5	–4
For profit	90	90	90	18	1	1	–2	1
Nonprofit	10	10	10	17	–1	–1	–7	–5
Two LDOs	75	74	75	18	1	1	–3	–0.1
All others	25	26	25	17	1	0	0	2

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.

and isolated (LVI) 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 current 0.8 percent rural-facility adjustment (Centers for Medicare & Medicaid Services 2024b).

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

Another component of access is whether providers have a financial incentive to expand the number of FFS Medicare beneficiaries they serve. To assess this component, we examine the FFS Medicare marginal profit—the percentage of revenue from FFS Medicare that is left as profit after accounting for the allowable variable costs of providing services to FFS Medicare patients. (Variable costs are those that vary with the number of patients treated. By contrast, fixed costs are those that are the same in the short run regardless of

the number of patients treated (e.g., rent).) If the FFS Medicare marginal profit is positive, a provider with excess capacity has a financial incentive to care for an additional FFS beneficiary; if the FFS Medicare marginal profit is negative, a provider may have a disincentive to care for an additional FFS beneficiary. (See the text box in Chapter 2 on the different margin measures MedPAC uses to assess provider profitability.)

FFS Medicare payments in 2023 exceeded dialysis facilities' marginal costs by an average of 17 percent, a positive indicator of patient access, in that facilities with available capacity have a financial incentive to treat FFS Medicare beneficiaries.

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

The decline in the number of FFS beneficiaries on dialysis and in FFS treatments accelerated considerably beginning in 2021, after the enactment of the 21st Century Cures Act.[13] As beneficiaries with ESRD shifted to MA in 2021 through 2023, the number of FFS beneficiaries on dialysis fell 12 percent per year, on average, and the number of FFS treatments fell 12 percent per year. The effect of removing the statutory bar is highlighted by the roughly 8 percent drop in the number of FFS dialysis treatments between December 2020 and January 2021 and the additional 31 percent drop in FFS treatments furnished between January 2021 and December 2023. Although the number of FFS beneficiaries on dialysis and the number of treatments declined between 2022 and 2023, the number of dialysis treatments per beneficiary per week remained steady at 2.8.[14]

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; thus, the more units of a drug 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-related drugs that were previously billed separately.

Table 5-4 shows changes between 2010 and 2023 (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.[15] We estimated per treatment use by multiplying ESRD drug units per treatment reported on CMS claims by each drug's 2023 average sales price (ASP) plus 0 percent—that is, holding price constant.[16] 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 5-4, 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 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 lead to increased risk of morbidity and mortality, which resulted in the Food and Drug Administration changing the ESA label in 2011.

Most recently, between 2022 and 2023, holding price constant, use across the five groups declined by 7 percent; this decline partly reflects the shift to less costly clinically similar products within a therapeutic group. For example, the share of FFS beneficiaries on dialysis who received epoetin beta increased between 2022 and 2023. 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 2022 and 2023, use (as measured by units per treatment) of epoetin beta and the epoetin alfa biosimilar increased while use of darbepoetin and epoetin alfa reference product 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 2022 and 2023 reflects changes in the share of FFS

TABLE 5–4

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 estimated use of ESRD drugs*	Percent of aggregate change between:		
	2010	2010–2011	2010–2023	2022–2023
ESAs	$41	–23%	–61%	–9%
Iron agents	4	–10	–24	–3
Vitamin D agents	2	–19	–73	–16
Calcimimetics	N/A	N/A	N/A	–4
Other drugs	2	–43	–85	–8

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, sodium ferric gluconate, ferumoxytol, and ferric carboxymaltose. 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. Since 2021, calcimimetics have been paid under the ESRD PPS base rate.
* 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 2023 average sales price (ASP) plus 0 percent. Because 2023 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 2023 dollars using the pharmaceutical Producer Price Index. By holding the price constant, we account for the different billing units assigned to a given drug.

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

beneficiaries on dialysis receiving an ESRD drug. Overall, the share of FFS beneficiaries on dialysis prescribed drugs to treat anemia—ESAs and iron agents—remained stable between 2022 and 2023, while the share of beneficiaries prescribed drugs that treat bone and mineral metabolism disorders—calcimimetics and vitamin D agents—declined by 1 percentage point and 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 program has revealed no sustained decline of beneficiary health status from January 2010 through December 2022 (Centers for Medicare & Medicaid Services 2023a).

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

In 2022 and 2023, use of the emergency department (ED) by FFS beneficiaries on dialysis, as well as their 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. In-center hemodialysis patient-experience measures also remained steady. Use of home dialysis and the number of kidney transplants increased during this period.[17]

Quality under the ESRD PPS

Our analysis of available claims and enrollment data for FFS beneficiaries on dialysis 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, averaging 2.0 percent per month in 2021 and 2022 and 1.9 percent in 2023.
- Between 2021 and 2023, 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 per month. During the same period, 30-day readmission rates on an annual basis remained relatively steady at 21 percent of admissions.

- Between 2021 and 2023, the share of FFS beneficiaries on dialysis who used the ED on an outpatient basis (beneficiaries with at least one ED visit in a given month) remained steady, averaging 18 percent per month.

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 2021 and 2023, the share of beneficiaries receiving adequate dialysis remained steady, averaging between 97 percent and 98 percent of beneficiaries on hemodialysis and between 92 percent and 93 percent of beneficiaries receiving peritoneal dialysis (PD). 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.[18] 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 2023, 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 2023, rates of blood transfusion remained relatively steady, averaging between 2.7 percent and 2.8 percent per month.

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, 60 percent to 80 percent gave the top ratings across the three composite and three global ratings (Table 5-5). Patient experience remained relatively stable between reporting years 2022 and 2024. Survey results did not differ between urban and rural facilities (data not shown).

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). The share of beneficiaries dialyzing at home steadily increased from 9 percent per month in 2011 to 17 percent per month in 2023. Differences by race have persisted over time: Although about 29 percent of FFS Medicare beneficiaries with ESRD are Black, only 23 percent of beneficiaries who dialyze at home are Black.

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 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).[19]

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 patients new to dialysis more than doubled, from 15 percent to 34 percent. To augment the use of home dialysis, the health care

TABLE 5–5

In-center hemodialysis patient experience scores, 2022–2024

ICH–CAHPS measures	2022	2023	2024
Share of patients giving top ratings for:			
Nephrologists' communication and caring	68%	67%	67%
Quality of dialysis center care and operations	64	64	64
Providing information to patients	80	79	79
Share of patients rating a 9 or 10 out of 10 (best possible):			
Rating of the nephrologist	61	59	59
Rating of the dialysis center staff	66	64	65
Rating of the dialysis facility	70	69	69

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 most favorable ratings for the first three measures include those who report "always," while ratings for the next three measures are the percentage of patients who gave a score of 9 or 10 on a scale of 0 (worst possible) to 10 (best possible). 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 2024 include surveys collected between April 2023 and December 2023. Among facilities reporting ICH–CAHPS data (2,308 facilities in reporting year 2024), the survey response rate ranged between 25 percent and 28 percent.

Source: CMS summary of national average for ICH–CAHPS survey measures, 2022–2024.

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 annual Medicare spending for patients on dialysis (roughly $98,000) was more than twice the annual spending for 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 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.

Between 2022 and 2023, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 7 percent, to 27,332 (Table 5-6, p. 166).[20] 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 2014 and 2023, the share of transplants for Black and Hispanic patients rose (Table 5-6).

TABLE 5–6 **Between 2022 and 2023, the number of kidney transplants increased**

	2014	2022	2023
Total transplants	17,108	25,500	27,332
Share of total transplants from live donors	32%	23%	23%
Share receiving a transplant			
White	50	41	40
Black	25	29	30
Hispanic	16	20	20
Asian	6	8	8
All others	2	2	2

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

Source: Organ Procurement and Transplantation Network.

Most dialysis providers appear to have adequate access to capital

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 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 (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 2023a).
- To optimize its portfolio, Fresenius Medical Care entered into an agreement in 2023 to sell National Cardiovascular Partners with 21 facilities providing outpatient cardiac-catheterization and vascular laboratory services (Fresenius Medical Care 2023d). In addition, Fresenius Medical Care announced completion of the first phase of the company's first global dialysis dataset, the Apollo database project, which is the company's foundation for its long-term artificial intelligence goals. The database is the largest multinational, longitudinal database of its kind. It is intended to advance patient quality and outcomes by making kidney-disease care more personalized and precise, and it provides information about the clinical care furnished to more than 540,000 patients on dialysis (Fresenius Medical Care 2023b).

In recent public financial filings, the two LDOs reported generally positive financial performance related to their dialysis business for 2024, including improvements in productivity and earnings growth (DaVita 2024d, Fresenius Medical Care 2024a). Both

companies reported improved operating income margins, operating income, and net income in the third quarter of 2024 compared with the third quarter of 2023. Other positive results reported by both LDOs as of the third quarter 2024 include higher growth in revenue per treatment compared with the cost of patient care per treatment (4 percent vs. 1 percent, respectively) (DaVita 2024d) and positive organic revenue growth (Fresenius Medical Care 2024a).

Since 2010, both LDOs 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 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 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. 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 2022, Part D spending on Velphoro for FFS beneficiaries on dialysis was nearly $250 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.) Using cost-report data submitted by freestanding dialysis facilities to CMS, we estimated that the 2023 all-payer margin was roughly 15 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.[21] 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 but about 32 percent of its revenues from U.S. dialysis patients, while patients with government coverage account for 90 percent of its treatments and 68 percent of its revenues from U.S. dialysis patients (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). 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 2023

Between 2022 and 2023, Medicare's payments per FFS dialysis treatment increased 3 percent while total costs per treatment rose by 2 percent. In 2023, the FFS Medicare margin rose to −0.2 percent from −1.1 percent in 2022. (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 2022 and 2023, FFS per capita annual spending for outpatient dialysis services (i.e., for dialysis treatments furnished by ESRD freestanding and hospital-based facilities) increased by 2 percent to nearly $31,000. Total FFS Medicare spending for these services, however, declined 8 percent from 2022, to $8.1 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 3 percent) increased the base ESRD PPS payment rate in 2023.

Between 2021 and 2022, Part D spending for ESRD oral-only phosphate binders declined for FFS beneficiaries on dialysis

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 regulation and statute); therefore, we track Part D spending for this group. Between 2021 and 2022 (the most recent year for which data are available), spending for phosphate binders furnished to FFS beneficiaries on dialysis declined by 13 percent to $0.7 billion.[22] The decline in total spending for phosphate binders for FFS beneficiaries on dialysis is linked to the substantial increase in beneficiaries on dialysis enrolling in MA in 2021. Among FFS beneficiaries on dialysis who used phosphate binders, per capita spending in 2021 and 2022 increased by 4 percent to $4,500 per patient. Similar shares (ranging from 66 percent to 68 percent) of FFS beneficiaries on dialysis with Part D coverage were prescribed phosphate binders in 2021 and 2022, and Part D spending for phosphate binders accounted for a similar share of their Part D spending in each year (ranging from 32 percent to 34 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, phosphate binders will be paid for under the ESRD PPS.[23] Dialysis facilities will 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).[24] 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 for all phosphate binders used in a month, 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, as such costs were not addressed when the ESRD PPS base rate was implemented in 2011 (Centers for Medicare & Medicaid Services 2024b). CMS and others expect that beneficiary access to phosphate binders will be increased by their inclusion in the ESRD PPS because not all FFS beneficiaries on dialysis are enrolled in Part D or have drug coverage comparable with Part D:

- According to CMS: "We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage, with significant positive health equity impacts" (Centers for Medicare & Medicaid Services 2024b).
- According to one of the LDOs: "Given our experience with calcimimetics, we strongly believe this [phosphate binders paid under the ESRD PPS] will provide more patients with access to these drugs since many of our patients do not have Part D coverage" (DaVita 2024c).

Providers' costs for outpatient dialysis services under the ESRD PPS

We examine aggregate dialysis-facility costs using 2022 and 2023 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 2022 and 2023, total cost per treatment rose by 2 percent, from $286 per treatment to nearly $291 per treatment.

- Labor and overhead costs increased by 4 percent and 14 percent, respectively, and accounted for 35 percent and 30 percent of 2023 providers' cost per treatment, respectively.
- Costs dropped for:
    - capital-related assets and laboratory services, which each declined by 8 percent and

accounted for 17 percent and 1 percent of the cost per treatment, respectively, in 2023; and

- ESRD drugs, which declined by 15 percent and accounted for 7 percent of cost per treatment in 2023, and supplies, which declined by 1 percent and accounted for 10 percent of providers' cost per treatment in 2023.

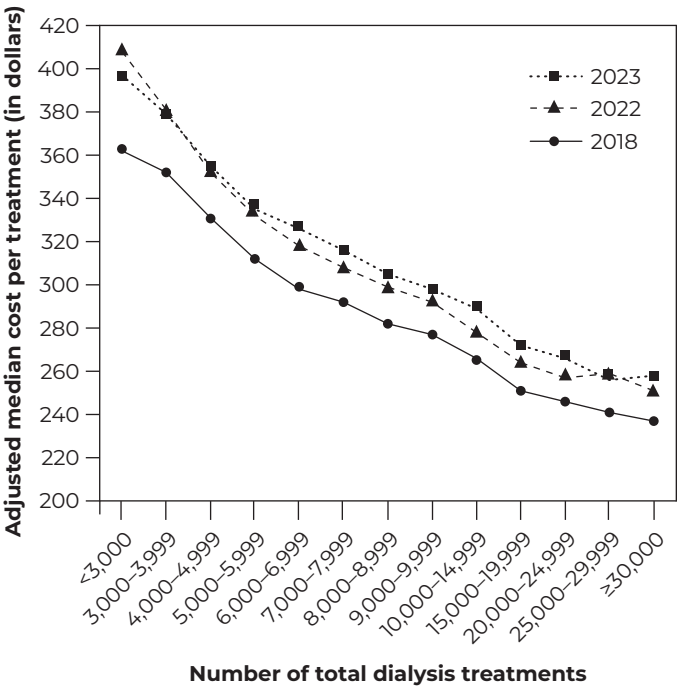
The 2 percent overall cost growth in 2023 is moderate compared with the 6 percent increase in cost per treatment between 2021 and 2022. The decline in cost growth in 2023 relative to 2022 is attributable to the drop in cost per treatment experienced by all cost categories except for labor and overhead. Our finding that labor costs grew more slowly in 2023 than in 2022 (4 percent per treatment vs. 7 percent per treatment, respectively) is consistent with announcements by the LDOs that their labor performance was better in 2023 than in 2022 (DaVita 2024b, Fresenius Medical Care 2023c). By contrast, overhead costs rose sharply in 2023 compared with 2022 (14 percent per treatment vs. 7 percent per treatment).

Variation in cost growth across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2022 and 2023, per treatment costs fell by 3 percent for facilities in the 25th percentile of cost growth, compared with a rise of 8 percent for facilities in the 75th percentile. The growth in cost per treatment is related to facility size. Between 2022 and 2023, 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 nearly 4 percent) compared with all other facilities (with cost growth averaging 2 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 2023, labor cost varied by $44 per treatment, and capital costs varied by $31 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).

FIGURE 5–4

Higher-volume freestanding dialysis facilities had lower cost per treatment, 2018–2023



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.

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 2018 and 2023 (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 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 2023.[25]

The 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 2.3 percent in 2021 and –1.1 percent in 2022. 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. 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 5-5). 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 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, however, the FFS Medicare margin increased due to the profitability of the calcimimetics paid under the TDAPA policy—to 2.1 percent in 2018 and 8.4 percent in 2019 (Figure 5-5).[26,27] 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 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. The increase in the FFS Medicare margin from –1.1 percent to –0.2 percent in 2023 is partly attributable to (1) lower capital, ESRD-drug, lab, and supply cost per treatment compared with 2022; (2) lower growth in labor cost per treatment compared with 2022 (4 percent vs. 7 percent, respectively); and (3) growth in the FFS payment per treatment exceeding the growth in providers' cost per treatment (DaVita 2022b, Fresenius Medical Care 2022). Partially offsetting these factors were increases in overhead cost per treatment between 2022 and 2023 and declining total treatment volume between 2022 and 2023. The two LDOs experienced a 0.3 percent decline in total treatment volume (across all payers) between 2022 and 2023 (DaVita 2024a, Fresenius Medical Care 2024b). Additionally, unlike in previous years, add-on payments (for the drug Korsuva and for the Tablo Hemodialysis System) may not have had a material effect on dialysis facilities' FFS Medicare margin because of the limited use of these services, as found by MedPAC analysis of claims data.

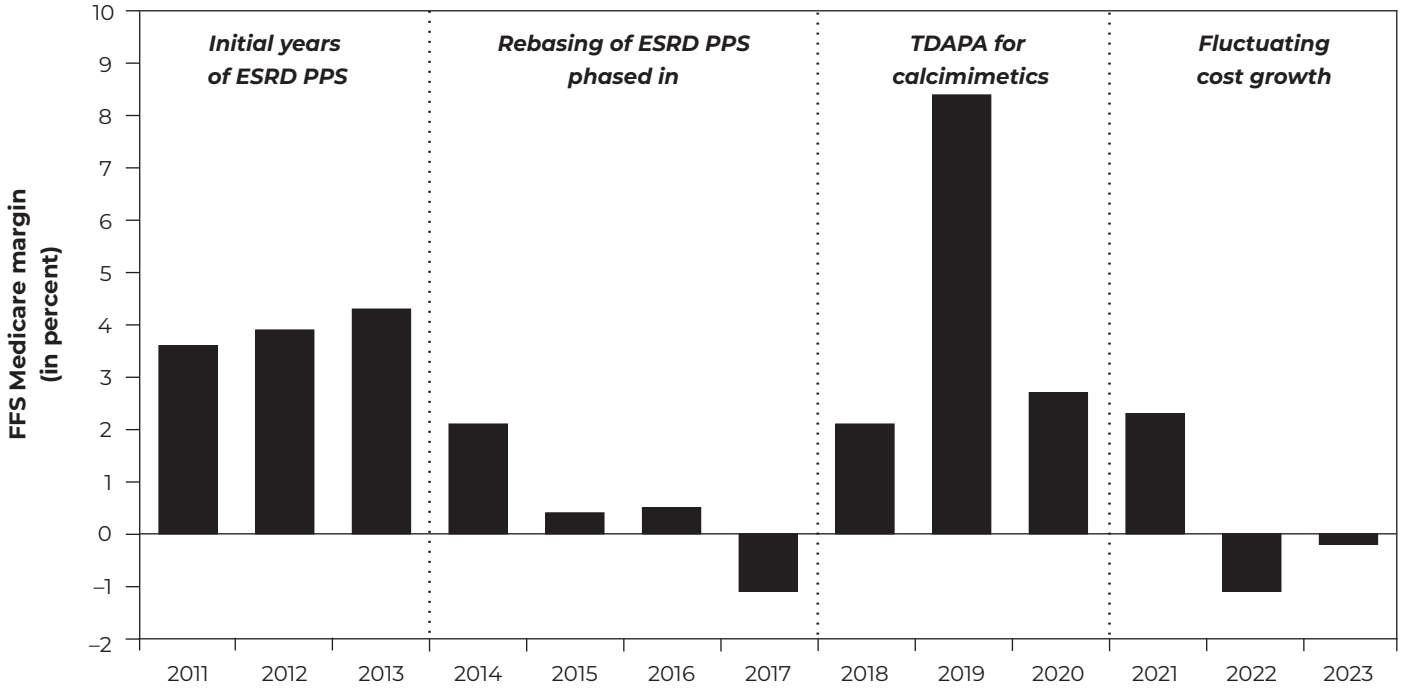
The FFS Medicare margin varies by treatment volume

FFS Medicare margins in 2023 decidedly varied by treatment volume: Facilities in the lowest-volume quintile had margins below –19 percent, while facilities in the top-volume quintile had margins of over 7 percent (Table 5-7, p. 172). Urban facilities averaged higher margins than rural facilities (0.6 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 2023, 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 5-4, p. 169).

Although some rural facilities in 2023 have benefited from the ESRD PPS's 23.9 percent low-volume adjustment (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

FIGURE 5–5

FFS Medicare margin has varied over time, but beneficiaries' access to care has remained stable



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.

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 will receive a 28.9 percent upward adjustment, and those furnishing between 3,000 and 3,999 treatments will receive an 18.3 percent upward adjustment per the two-tiered LVPA policy finalized in the 2025 ESRD PPS final rule. CMS contends that this modification will better target payment increases to facilities with higher costs (Centers for Medicare & Medicaid Services 2024b). 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).

Projecting payments and costs for 2025

We project that the FFS Medicare margin will slightly increase in 2025, to 0 percent in aggregate. To estimate the projected 2025 margin, the Commission considers providers' cost growth between 2018 and 2023 and policy changes affecting payments in 2024 and 2025. These factors include:

- statutory updates to the dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) of 2.1 percent in 2024 and 2.2 percent in 2025;

TABLE 5–7

In 2023, 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	–0.2%	100%	100%
Urban	0.6	84	88
Rural	–4.5	16	12
Treatment volume (quintile)			
Lowest	–19.0	20	8
Second	–11.2	20	13
Third	–3.3	20	18
Fourth	1.6	20	24
Highest	7.5	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.

- reductions in payments of 0.16 percent in 2024 and 0.37 percent in 2025 due to the ESRD Quality Incentive Program; and
- reductions in payments in 2024 and 2025 due to the ETC Model (CMS Innovation Center's mandatory model), which CMS estimates will total $10 million in 2024 and $14 million in 2025 (Centers for Medicare & Medicaid Services 2024b).

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

- add-on payments in 2024 and 2025 for new ESRD drugs (daprodustat that treats anemia, difelikefalin that treats pruritus, and taurolidine and heparin sodium that reduce incidence of catheter-related bloodstream infections) and in 2025 for phosphate binders; and
- both LDOs' productivity efficiencies in 2024; 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.

How should FFS Medicare payments change in 2026?

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 2025 is low. Under current law, Medicare's base payment rate under the ESRD PPS will be increased in 2026 based on the forecasted increase in the ESRD market basket less a forecasted increase in productivity. The final update for 2026 will not be set until summer 2025, but CMS currently forecasts a 1.7 percent increase in the base payment rate. The final 2026 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 under a TDAPA and a 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 between 2018 and 2020 (Figure 5-5, p. 171). Although some stakeholders have raised concerns that paying for phosphate binders under the ESRD PPS may have a negative effect on their 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 (Centers for Medicare & Medicaid Services 2024b, Government Accountability Office 2023).

Indeed, 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 slowly declining incidence of ESRD over the past decade.

RECOMMENDATION 5

For calendar year 2026, the Congress should update the 2025 Medicare base payment rate for outpatient dialysis services 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 ESRD drugs under the ESRD PPS. Indicators of quality of care have generally remained stable. The FFS Medicare margin was −0.2 percent in 2023 and is projected to be 0 percent in 2025. 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 2024 and 2025, 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; for example, each reported increasing treatment volume and decreasing mortality, and both achieved productivity gains in 2024 (DaVita 2023b, Fresenius Medical Care 2023c). Low-volume dialysis facilities, which tend to have higher costs due to fewer economies of scale, may be helped by increased payments paid 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 1.7 percent in 2026. This recommendation would have no effect on federal program spending relative to the statutory update.

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 The term "excess death" refers to the difference between observed and expected deaths based on historical trends. For example, Kim and researchers estimated that among persons with ESRD, the number of observed deaths during the coronavirus pandemic between March and August 2020 was 16 percent higher than the expected number of deaths, and excess deaths were substantially higher among Black and Hispanic persons with ESRD (Kim et al. 2021). More discussion of this topic can be found at https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch6_v2_SEC.pdf.

4 Our analyses of CMS enrollment and supplemental coverage data show that in 2023, approximately 43 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 26 percent of all other FFS beneficiaries without cost sharing covered by Medicaid.

5 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, but only 26 states require insurers to offer a plan to those entitled to Medicare due to ESRD (American Kidney Fund 2024, Freed et al. 2024).

6 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, through need-based grants to pay for health insurance premiums, prescription medications, and other items and services.

7 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.

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

9 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.

10 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 estimated expenditure levels for the given ESRD drug in the prior year.

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 the 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/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 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).

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

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

16 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 2023 average ASP, with one exception. Because 2023 ASP data were not available for cinacalcet, we used CMS's TDAPA payment limit for the fourth quarter of 2020 and updated it to 2023 dollars using the pharmaceutical Producer Price Index. By holding the price constant, we account for the different billing units assigned to a given drug.

17 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.

18 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.

19 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).

20 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.

21 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.

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

23 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.

24 In the final rule, CMS said that the agency intends to reevaluate the amount of the monthly fixed-rate addition in next year's rulemaking.

25 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.

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

27 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).

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