

CHAPTER

6

Outpatient dialysis services

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

- 6** For calendar year 2024, the Congress should update the 2023 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

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

Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2021, nearly 332,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from more than 7,800 dialysis facilities. In 2021, Medicare expenditures for outpatient dialysis services totaled \$10.0 billion.

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 payments are adequate.

- **Capacity and supply of providers**—Dialysis facilities appear to have the capacity to meet demand. Between 2020 and 2021, the number of in-center treatment stations grew faster than the number of FFS and Medicare Advantage (MA) dialysis beneficiaries.
- **Volume of services**—The steep (20 percent) decline in FFS treatments in 2021 is largely due to the removal of the statutory provision that

In this chapter

- Are Medicare payments adequate in 2023?
- How should Medicare payments change in 2024?

prevented most dialysis beneficiaries from enrolling in MA plans. Between January 2020 and December 2021, the share of dialysis beneficiaries enrolled in MA plans increased from 25 percent to roughly 40 percent. The effects of the pandemic's excess mortality also contributed to the decline in FFS treatments in 2021. At the same time, use of ESRD drugs in the payment bundle (including erythropoiesis-stimulating agents, which are used in anemia management) continued their decade-long decline.

- **Marginal profit**—An estimated 20 percent marginal profit in 2021 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries.

Quality of care—FFS dialysis beneficiaries' rates of all-cause hospitalization and mortality increased somewhat between 2020 and 2021, while emergency department use remained steady. The share of beneficiaries dialyzing at home, which is associated with better patient satisfaction, continued to grow.

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

Medicare payments and providers' costs—Medicare payment per treatment in freestanding dialysis facilities (which provide the vast majority of FFS dialysis treatments) grew by 0.9 percent while cost per treatment rose by 1.3 percent. Growth in costs was seen across all cost categories, with the exception of ESRD drugs. The aggregate Medicare margin fell from 2.7 percent in 2020 to 2.3 percent in 2021 (2.7 percent including provider-relief pandemic revenues). We project that the 2023 aggregate Medicare margin will drop to -0.4 percent, due to cost growth that we expect will exceed payment updates.

How should Medicare payments change in 2024?

Under current law, the Medicare FFS base payment rate for dialysis services is projected to increase by 1.8 percent in 2024. Given that most of our indicators of payment adequacy are positive, the Commission recommends that, for 2024, the Congress update the calendar year 2023 ESRD PPS base rate by the amount determined under current law. ■

Dialysis treatment choices

Dialysis replaces the filtering function of the kidneys when they fail. The two types of dialysis—hemodialysis and peritoneal dialysis (PD)—remove waste products from the bloodstream differently. Most dialysis patients travel to a treatment facility to undergo hemodialysis three times per week, although patients can also undergo hemodialysis at home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient’s blood. By contrast, PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed independently in the patient’s home or workplace five to seven days a week.

Each dialysis method has advantages and drawbacks; no one method is best for everyone. People choose a particular dialysis method for many reasons, including quality of life, patients’ awareness of different treatment methods and personal preferences, and physician training and recommendations. Some patients switch methods when their conditions or needs change. Although most patients still undergo in-center dialysis, home dialysis remains a viable option for many patients because of such advantages as increased patient satisfaction, better health-related quality of life, and fewer transportation challenges compared with in-center dialysis. ■

Background

End-stage renal disease (ESRD) is the last stage of chronic kidney disease (CKD) and is characterized by permanent, irreversible kidney failure. Patients with ESRD include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and the variation in patients’ suitability for transplantation, about 70 percent of ESRD patients undergo maintenance dialysis (see text box on dialysis treatment choices). Patients receive additional items and services related to their dialysis treatments, including ESRD drugs and biologics to treat conditions such as anemia and bone disease resulting from the loss of kidney function.

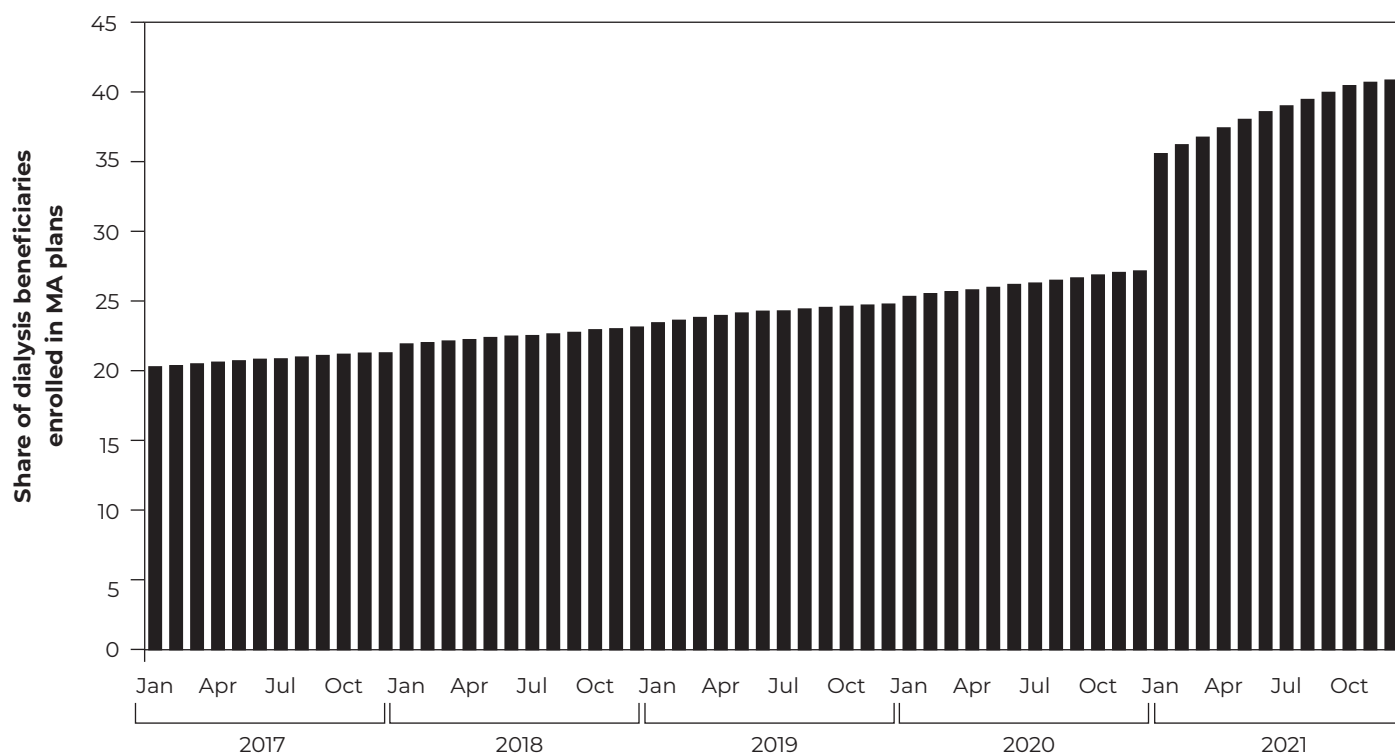
In 2021, nearly 332,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 7,880 dialysis facilities.^{1,2} Since 2011, Medicare has been paying facilities using a prospective payment system (PPS) bundle that includes ESRD drugs (for which facilities previously

received separate payments) and services (for which other Medicare providers, such as clinical laboratories, previously received separate payments).³ In 2021, Part B spending for Medicare-covered outpatient dialysis services was \$10.0 billion. Additionally, in 2020 (the most recent data available), Part D payments for ESRD oral-only drugs that were not yet included in the PPS—several phosphate binders—totaled \$0.9 billion.⁴ In 2021, no renal drug, equipment, or supply qualified for a transitional add-on payment under the ESRD PPS.

Medicare is the main source of health care coverage for individuals with ESRD.⁵ Historically, dialysis beneficiaries generally had FFS coverage, as they were prohibited from enrolling in Medicare Advantage (MA) plans. However, beneficiaries who enrolled in a managed care plan before being diagnosed with ESRD could stay in the plan after they were diagnosed. Over time, the share of dialysis beneficiaries enrolled in MA gradually increased. Between 2017 and 2020, the share of dialysis beneficiaries in MA rose from about 20 percent to 27 percent, while the share of dialysis beneficiaries in FFS fell from about 80 percent to 73 percent (Figure 6-1, p. 174; FFS data not shown).

**FIGURE
6-1**

Share of dialysis beneficiaries enrolling in MA plans increased between 2020 and 2021



Note: MA (Medicare Advantage). Beginning in 2021, the 21st Century Cures Act permits dialysis beneficiaries to enroll in MA plans. As a result of this statutory change, enrollment of dialysis beneficiaries in MA plans spiked between December 2020 and January 2021 from 27 percent to 36 percent.

Source: Data compiled by MedPAC from CMS enrollment data.

Beginning in 2021, the 21st Century Cures Act permits dialysis beneficiaries to enroll in MA plans. As a result of this statutory change, enrollment of dialysis beneficiaries in MA plans spiked between December 2020 and January 2021 from 27 percent to 36 percent (Figure 6-1). By December 2021, the share of dialysis beneficiaries enrolled in MA plans exceeded 40 percent.

The increase in MA enrollment by dialysis beneficiaries since January 2021 is likely linked to the same factors that have increased MA's popularity among non-ESRD beneficiaries, including the availability of extra benefits (e.g., dental, hearing, and vision services) and lower cost-sharing liability. In 2023, the average MA plan enrollee has access to over \$2,350 in extra

benefits annually that Medicare FFS enrollees cannot access without purchasing additional health insurance coverage or paying for the services on an out-of-pocket basis (see Chapter 11). Given the magnitude of total health care expenses incurred by dialysis patients (for dialysis and other outpatient and inpatient services—on average, nearly \$95,000 in 2020), these beneficiaries face significant out-of-pocket cost-sharing liability and may seek to enroll in an MA plan because such plans generally offer reduced cost sharing and are required to offer a maximum out-of-pocket (MOOP) limit on annual spending. The mandatory MOOP limit was \$7,550 for in-network services in 2022 (and \$11,300 for in-network and out-of-network services covered by preferred provider organizations (PPOs)), but most plans can elect to offer a lower MOOP limit.

In 2022, the average MOOP was \$4,972 for in-network services (and \$9,245 for in-network and out-of-network services covered by PPOs) (Freed et al. 2022).⁶ Beneficiaries who have full Medicaid coverage (about 41 percent of Medicare beneficiaries with ESRD and 15 percent of other Medicare beneficiaries) have their cost sharing covered by Medicaid but may still enroll in an MA plan for the extra benefits offered.⁷

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

- Constraints in federal guaranteed-issue rights in obtaining these supplemental plans. Medicare beneficiaries have guaranteed-issue rights for Medigap plans—meaning that a plan must be offered regardless of their age, sex, or health status—when they turn 65. However, about half of individuals with ESRD become eligible for Medicare before reaching age 65, and federal guaranteed-issue rights do not extend to those beneficiaries at the time of their initial enrollment in Medicare. 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, gender, or health status. Outside of the federal guaranteed-issue window, Medigap plans offered to beneficiaries with ESRD are limited; 35 states require insurers to offer at least one Medigap plan to beneficiaries under age 65, but only 30 states require insurers to offer a plan to those entitled to Medicare due to ESRD rather than because of disability (AARP 2022, American Kidney Fund 2022).
- The affordability of a Medigap plan. Even though beneficiaries with ESRD who are under 65 must be offered at least one Medigap plan in 35 states, the insurer can charge a higher premium based on age, sex, or existing health conditions, depending on state insurance rating rules. Some FFS dialysis beneficiaries get financial assistance from the American Kidney Fund, a nonprofit organization

whose funding sources include dialysis providers and pharmaceutical manufacturers, via need-based grants to pay for health insurance premiums, prescription medications, and other items and services.

In addition to MA plans, dialysis beneficiaries residing in selected geographic areas have access to ESRD special needs plans (SNPs) (specifically, C-SNPs, a type of SNP for individuals with chronic conditions). As of November 2022, few dialysis beneficiaries—about 4,500—were enrolled in 12 ESRD SNPs in 9 states (Arizona, California, Colorado, Connecticut, Kentucky, New Jersey, New Mexico, Texas, and Virginia).

Dialysis patients are logical candidates for coordinated care programs, such as specialty-oriented accountable care organizations (ACOs) and the ESRD C-SNPs. Patients are medically complex because they often have multiple chronic conditions in addition to renal failure, including heart failure, diabetes, and hypertension. Moreover, patients either receive in-center treatment thrice weekly or have a regular evaluation at the dialysis facility if being treated at home. Shared savings and coordinated care arrangements have shown promise to improve the care of dialysis beneficiaries. For example, a plan-sponsored data analysis from one ESRD C-SNP found lower hospital admissions and a decreased likelihood of mortality compared with patients treated in the same facilities or facilities located in similar counties (Becker et al. 2020).

Characteristics of fee-for-service dialysis beneficiaries, 2021

Compared with other Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately younger, male, and Black (Table 6-1, p. 176). In 2021, 74 percent of FFS dialysis beneficiaries were under 75 years old, 57 percent were male, and 33 percent were Black. By comparison, among other FFS Medicare beneficiaries, 63 percent were under 75 years old, 47 percent were male, and 9 percent were Black. A greater share of dialysis beneficiaries resided in urban areas compared with other FFS beneficiaries (83 percent vs. 80 percent).

FFS dialysis beneficiaries are more likely to have full Medicaid benefits than all other FFS beneficiaries (41 percent vs. 15 percent). In addition, in 2021, FFS dialysis beneficiaries were less likely to have coverage

**TABLE
6-1**

FFS dialysis beneficiaries are disproportionately young, male, and Black compared with all other Medicare FFS beneficiaries, 2021

Share of FFS beneficiaries:

	Dialysis beneficiaries	All other beneficiaries
Age		
Under 45 years	10%	3%
45–64 years	35	9
65–74 years	29	51
75–84 years	19	27
85+ years	6	10
Sex		
Male	57	47
Female	43	53
Race		
White	47	81
Black	33	9
Hispanic	8	3
Asian	4	3
All others	7	5
Residence, by type of county		
Urban	83	80
Micropolitan	10	11
Rural, adjacent to urban	5	5
Rural, not adjacent to urban	2	3
Frontier	1	1

Note: FFS (for-for-service). “All other beneficiaries” excludes beneficiaries on dialysis and those who have received a kidney transplant. “Residence” reflects the beneficiary’s county of residence in one of four categories (urban, micropolitan, rural adjacent to urban, and rural nonadjacent to urban) based on an aggregation of the Urban Influence Codes. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

Source: Data compiled by MedPAC from enrollment data and claims submitted by dialysis facilities to CMS.

from other sources, such as Medigap and employer-sponsored health plans (35 percent vs. 62 percent) and as likely to have no supplemental coverage (about 24 percent for each group in 2021).

Over the last decade, the adjusted rate of new ESRD cases, or incidence rate (which includes patients of all types of health coverage who initiate dialysis or

receive a kidney transplant), has declined. Between 2010 and 2020 (the most recent year of data available), the adjusted incidence rate decreased by 1 percent per year, from 412 per million people to 363 per million people (United States Renal Data System 2022). We estimate that about 71,000 FFS beneficiaries began dialysis in 2021 (a decline of nearly 3 percent compared with 2020).

Medicare pays for dialysis services under the ESRD PPS

To treat ESRD, dialysis beneficiaries receive care from two principal providers: (1) the clinicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary's plan of care and (2) facilities that provide dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Medicare uses different methods to pay for ESRD clinician and facility services. Clinicians receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis-related management services (which includes managing the dialysis prescription and prescribing ESRD drugs); payment varies based on the number of visits per month, the beneficiary's age (adult vs. pediatric beneficiaries under 20 years of age), and whether the beneficiary receives dialysis in a facility or at home. While our work in this report focuses on Medicare's payments to facilities, it is important to recognize that facilities and clinicians collaborate to care for dialysis beneficiaries.

The ESRD PPS, established in 2011, encouraged providers to be more efficient. Specifically, the PPS payment bundle included (1) Part B ESRD drugs, laboratory tests, and other ESRD items and services that were previously billable separately and (2) Part D dialysis oral-only drugs—calcimimetics and phosphate binders (at that time). Clinicians use drugs in these two therapeutic classes to manage mineral bone disorders, a complication of advanced CKD.

Under the outpatient ESRD PPS, the unit of payment is a single dialysis treatment. For adult dialysis beneficiaries, the base payment rate does not differ by type of dialysis—in-center dialysis versus home dialysis—but rather by patient-level characteristics (age, body measurement characteristics, onset of dialysis, and selected acute and chronic comorbidities) and facility-level factors (low treatment volume, rural location, and local input prices).⁸ Medicare pays facilities furnishing dialysis treatments in the facility or in a patient's home for up to three treatments per week, unless the additional dialysis treatments are reasonable and necessary and there is documented medical justification for more than three weekly treatments.⁹

Since it was implemented in 2011, the outpatient ESRD PPS has undergone several significant changes. In 2014, CMS rebased the base payment rate, as mandated by the American Taxpayer Relief Act of 2012, to account for the decline in ESRD drug use under the ESRD PPS.¹⁰ In 2016, the agency recalibrated and redefined the patient-level and facility-level payment adjusters that are used to calculate each patient's adjusted payment per treatment.¹¹ In addition, in 2018, 2019, and 2020, transitional add-on payments were used to pay for certain drugs (calcimimetics) and were available for qualifying equipment and supplies.

Transitional add-on payments for new drugs, devices, and equipment

CMS uses transitional add-on payment policies for:

- **ESRD oral-only drugs that were intended to be in the bundle in 2011 but were delayed due to actions by regulatory and statutory provisions.** With the availability of an injectable calcimimetic in 2017, CMS no longer considered these drugs oral only and, between 2018 and 2020, the ESRD PPS paid for them using a transitional drug add-on payment adjustment (TDAPA).^{12,13} Since 2021, CMS has paid for calcimimetics under the PPS bundled payment rate.
- **New ESRD drugs in a new ESRD functional category.** To comply with the statute's mandate for including new ESRD-related injectable and intravenous drugs in the prospective payment bundle, the agency finalized a policy in 2016 that pays a TDAPA for new ESRD-related injectable drugs not in 1 of 11 ESRD-related functional categories of drugs included in the PPS payment bundle.¹⁴ (Functional categories are similar to therapeutic classes of drugs and are based on physiologic end-point action, including products used for anemia, bone and mineral metabolism, and antipruritic management.) For a new renal dialysis drug that is used to treat or manage a condition that does not fit into the current ESRD PPS functional categories, CMS will pay providers a TDAPA based on the product's average sales price (ASP) until sufficient claims data for rate setting analysis is available, but not for less than two years. During this period, CMS will assess whether to add a new functional category or refine an existing

functional category, as well as how to add the drug to the ESRD base rate (Centers for Medicare & Medicaid Services 2015).

- **Certain new ESRD drugs in an existing ESRD functional category.** CMS expanded the TDAPA policy in 2020 to apply to new ESRD drugs in an existing functional category (based on the agency’s statutory authority). CMS pays a TDAPA using the product’s ASP for a two-year period; thereafter, the drug is included in the PPS bundle without any change to the ESRD PPS base rate. CMS does not apply a substantial clinical improvement criterion to determine a new drug’s eligibility. Drugs that do not qualify for this TDAPA include generic equivalents and new dosage forms of an active ingredient that the Food and Drug Administration (FDA) has already approved, among others.¹⁵ As of April 2022, CMS pays a TDAPA for Korsuva (in the antipruritic functional category) for a two-year period (through March 31, 2024).¹⁶
- **New ESRD equipment and supplies that are not capital assets and home dialysis machines (a capital asset) when used in the home for a single patient.** Based on its regulatory authority, CMS pays a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for a two-year period; thereafter, these items are included in the PPS payment bundle without any change to the ESRD PPS base rate. Unlike for ESRD drugs, a substantial clinical improvement standard is used to determine eligibility under this transitional payment policy.¹⁷ CMS sets the new item’s payment rate at 65 percent of the price that the Medicare administrative contractors establish.¹⁸ As of January 2022, CMS pays a TPNIES for a home dialysis machine.

Are Medicare payments adequate in 2023?

To address whether payments for 2023 are adequate to cover the costs that efficient providers incur and how much providers’ costs are likely to change in the update year (2024), 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.

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 Medicare dialysis beneficiaries under the PPS—shows that beneficiaries’ access to care remains favorable.

Capacity has exceeded demand from dialysis patients across all insurance types

Growth in the number of dialysis facilities and in-center treatment stations alongside growth in the number of dialysis beneficiaries suggests that, between 2017 and 2020, provider capacity has exceeded FFS beneficiaries’ demand for care. During that period, the number of facilities and their capacity to provide care—as measured by dialysis treatment stations—each grew by 3 percent annually (Table 6-2, p. 180), compared with a 1 percent decline in the annual growth of the number of FFS dialysis beneficiaries (data not shown). In-center capacity also exceeded demand from all dialysis patients, across all insurance types, not just FFS beneficiaries. During the same period, the number of dialysis patients of all types of health coverage grew 1 percent per year (data not shown) (United States Renal Data System 2022).

The number of facilities’ in-center treatment stations grew more slowly annually between 2020 and 2021 compared with growth from 2017 through 2020 (1 percent per year vs. 3 percent per year) but exceeded growth in the number of dialysis FFS or MA beneficiaries (which declined about 2 percent between 2020 and 2021). The slower growth of in-center capacity may be partly attributable to the coronavirus pandemic.¹⁹ In addition, researchers have shown that the ESRD PPS was associated with an increase in home dialysis use among patients starting dialysis (Lin et al. 2017). Lastly, the financial incentives associated with Center for Medicare & Medicaid Innovation’s (CMMI’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 dialysis beneficiaries

and penalties for not increasing these outcomes—might have spurred some providers and clinicians to recommend home dialysis more often.²⁰

Between 2020 and 2021, capacity at freestanding and for-profit facilities each grew by 2 percent, while capacity at hospital-based facilities fell by 2 percent, and capacity at nonprofit facilities fell by 0.1 percent. During this period, capacity at urban facilities grew by 2 percent, while capacity at all rural facilities increased by 0.2 percent. In June 2020, the Commission recommended that the Secretary replace the current low-volume payment adjustment and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment—to better protect isolated, low-volume dialysis facilities that are critical to ensuring beneficiary access. The Commission found that the facilities that would receive the LVI adjustment would be more appropriately targeted compared with current policy (Medicare Payment Advisory Commission 2020).

Based on data from Medicare claims, freestanding dialysis cost reports, and CMS's Dialysis Facility Compare database, roughly half of facilities offered home dialysis between 2014 and 2021. Among facilities that furnished home dialysis, the share of total treatments furnished in the home rose from an average of 24 percent to 30 percent. (At the 75th percentile of facilities, the share increased from 28 percent to 34 percent, consistent with a rise in the share of FFS dialysis beneficiaries receiving home dialysis.)

Providers of outpatient dialysis services In 2021, there were 7,879 dialysis facilities in the United States that furnished about 35.6 million Medicare-paid treatments to FFS dialysis beneficiaries. In 2021, FFS Medicare accounted for 47 percent of all treatments furnished.²¹ According to CMS facility survey data, since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments. In 2021, freestanding facilities furnished 96 percent of FFS treatments, and for-profit facilities furnished 89 percent (Table 6-2, p. 180). In 2021, the capacity of facilities in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

The dialysis sector is highly consolidated, with two large dialysis organizations (LDOs)—Fresenius Medical Care and DaVita—dominating the industry. In 2021,

these LDOs accounted for three-quarters of facilities and Medicare treatments. In addition, 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.

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

Types of facilities that closed and their effect on

beneficiaries' access to care Each year, we examine the types of facilities that closed and whether certain groups of Medicare dialysis beneficiaries are disproportionately affected by facility closures. Using facilities' claims submitted to CMS and CMS's Dialysis Compare database and Provider of Services file, we compare the characteristics of beneficiaries treated by facilities that closed in 2020 with those of beneficiaries treated at facilities providing dialysis in 2020 and 2021.

Between 2020 and 2021, the number of dialysis treatment stations—a measure of providers' capacity—rose by 1 percent (Table 6-2, p. 180). During this time, there was a net increase in the number of freestanding facilities and in the number located in urban areas. Compared with facilities that treated beneficiaries in both years, our preliminary analysis suggests that facilities that closed in 2020 (about 40 facilities) were more likely to be hospital based, nonprofit, and small (as measured by the number of dialysis treatment stations), which is consistent with long-term trends in the supply of dialysis providers.

According to our analysis, few dialysis FFS beneficiaries (roughly 1,300 individuals) were affected by facility closures in 2020. Our analysis found that beneficiary groups who were disproportionately affected included Black FFS dialysis beneficiaries and FFS dialysis beneficiaries residing in urban areas. However, facility closures affected only 0.3 percent of all FFS dialysis

**TABLE
6-2**

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

	2021				Average annual percent change			
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities		Number of stations	
					2017–2020	2020–2021	2017–2020	2020–2021
All	35.6	7,879	137,900	18	3%	2%	3%	1%
	Share of total							
Freestanding	96%	95%	96%	18	3	2	4	2
Hospital based	4	5	4	14	-3	-1	-3	-2
Urban	86	84	86	18	4	2	4	2
Micropolitan	10	10	9	16	1	1	1	0.2
Rural, adjacent to urban	3	4	3	14	0.2	0	1	0.3
Rural, not adjacent to urban	1	2	1	12	-2	0	-1	0.4
Frontier	0.3	0.4	0.2	10	-1	3	1	3
For profit	89	89	89	18	3	2	4	2
Nonprofit	11	11	11	17	1	-1	1	-0.1
Two largest dialysis organizations	76	75	76	18	4	1	4	2
All others	24	25	24	17	1	2	1	1

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

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

beneficiaries. Our analysis of claims data suggests that beneficiaries affected by these closures obtained care elsewhere.

Volume of services

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

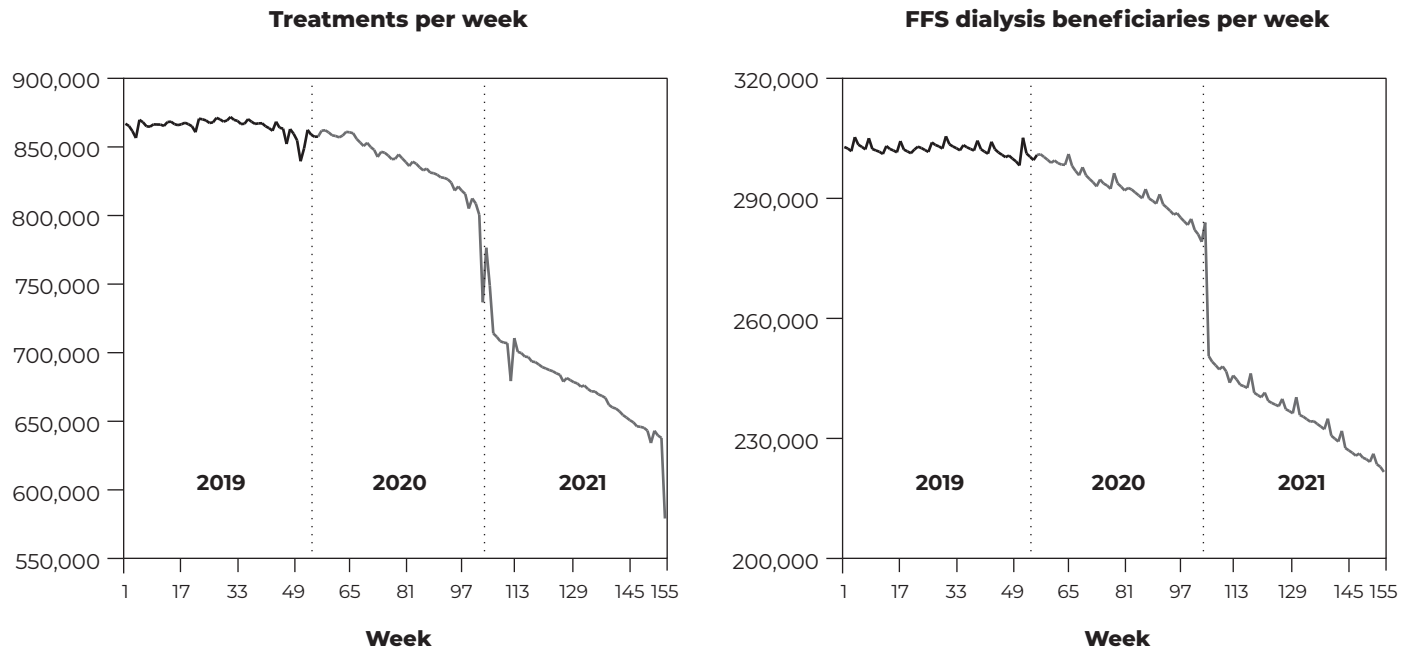
Trends in number of dialysis treatments provided

From 2017 to 2019, there was little change in the number of FFS dialysis beneficiaries and the number

of FFS dialysis treatments provided, but since then, both have declined sharply. In 2020, the number of FFS dialysis beneficiaries and dialysis treatments each declined by 3 percent due to the coronavirus pandemic, which slowed the initiation of dialysis by new patients and caused excess mortality among patients with ESRD. In 2021, the decline in the number of FFS dialysis beneficiaries and treatments accelerated, with the number of beneficiaries falling 14 percent and the number of treatments falling 20 percent. This drop was largely due to dialysis beneficiaries opting to enroll in MA plans after the enactment of the 21st Century Cures

**FIGURE
6-2**

Between 2019 and 2021, weekly number of FFS dialysis beneficiaries and treatments declined



Note: FFS (fee-for-service). The decline between 2019 and 2020 in the weekly number of FFS beneficiaries and treatments is largely attributable to the coronavirus pandemic, which resulted in slowing the initiation of dialysis by new patients and in excess mortality. The decline between 2020 and 2021 is largely attributable to enactment of the 21st Century Cures Act, which permits beneficiaries with ESRD to enroll in Medicare Advantage plans starting in 2021. The variation in the weekly number of beneficiaries and treatments may be linked to seasonal factors.

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

Act, which eliminated restrictions on the enrollment of beneficiaries with ESRD in MA (Figure 6-1, p. 174).²² Overall, in 2021, 332,000 beneficiaries received 35.6 million dialysis treatments. Although FFS beneficiaries and treatments declined between 2019 and 2021, the number of dialysis treatments per beneficiary per week remained steady at 2.9 (data not shown).

Figure 6-2 shows the effect of both the pandemic and the statutory change (that allows for ESRD beneficiaries to enroll in MA) on the weekly number of FFS dialysis beneficiaries and treatments. For example, the effect of the pandemic is highlighted by the 6 percent drop in the average weekly FFS dialysis treatments furnished between December 2019 and December 2020. The effect of removing the statutory bar is highlighted by

the 9 percent drop in the average number of weekly FFS dialysis treatments between December 2020 and January 2021 and the additional 13 percent drop between January 2021 and December 2021. Some variation in the weekly number of beneficiaries and treatments is also linked to seasonal factors.²³

Use of most ESRD-related drugs has declined, with no sustained negative changes in beneficiaries' outcomes
Under the ESRD payment method used before 2011, ESRD-related drugs were paid according to the number of units of the drug administered; in other words, the more units of a drug provided, the higher the Medicare payment. The ESRD PPS increased the incentive for providers to be more judicious in providing ESRD drugs included in the payment bundle. When CMS broadened

**TABLE
6-3**

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

Dialysis drug	Mean units per treatment ^a			Aggregate percent change	
	2010	2020	2021	2010–2021	2020–2021
ESAs					
Epoetin alfa (reference biologic)	5,214	1,103	1,051	-80%	-5%
Darbepoetin alfa	1.26	0.8	0.9	-32	2
Epoetin beta	N/A	4.2	4.2	N/A	-2
Epoetin alfa (biosimilar)	N/A	77	111	N/A	44
Iron agents					
Sodium ferric gluconate	0.15	0.06	0.05	-67	-17
Iron sucrose	16.0	12.5	13.7	-14	10
Bone and mineral metabolism agents					
Paricalcitol	2.3	0.2	0.2	-93	-27
Doxercalciferol	0.9	1.3	1.2	44	-4
Calcitriol	0.13	0.02	0.01	-91	-37
Cinacalcet	N/A	18.2 ^b	19.5 ^c	N/A	7
Etelcalcetide	N/A	5.5 ^b	2.0 ^c	N/A	-64
Other drugs					
Daptomycin	0.22	0.05	0.08	-62	82
Vancomycin	0.02	0.01	0.01	-63	21
Levocarnitine	0.010	0.001	0.001	-93	19
Alteplase	0.020	0.002	0.003	-87	26

Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not applicable [because drug not available in the U.S.]). Individual units per treatment are rounded; the aggregate percent change is calculated using unrounded units per treatment.

^aEach drug is reported using its own drug units.

^bIn 2020, cinacalcet and etelcalcetide were paid on a per unit basis under the ESRD transitional drug add-on payment policy.

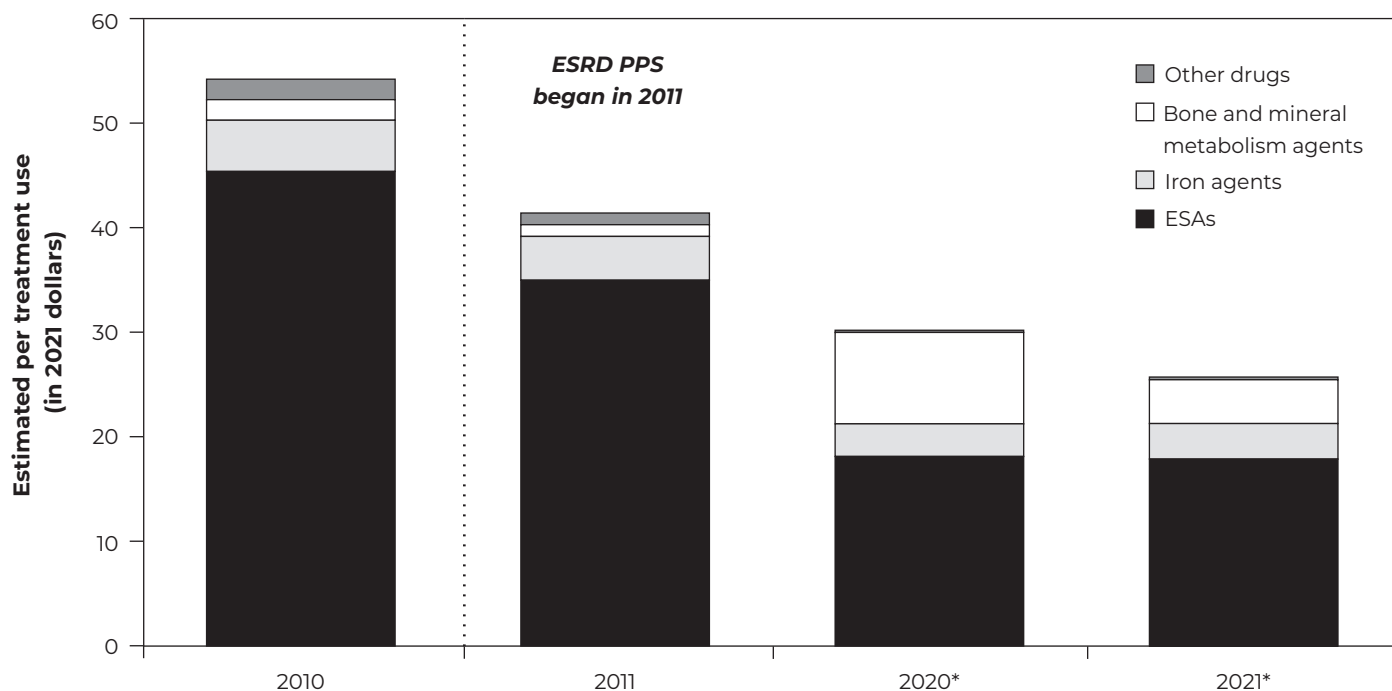
^cIn 2021, cinacalcet and etelcalcetide were included in the ESRD PPS payment bundle.

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

the payment bundle in 2011 to include ESRD-related drugs that previously were billed separately, the agency set the PPS payment rate on a per treatment basis using claims data from 2007. In 2014, to account for the decline in ESRD drug use under the ESRD PPS, the statute required that CMS rebase the PPS base rate by comparing drug use in 2007 with such use in 2012. Consequently, we examined changes between 2007 and 2021 (the most current year for which complete data are available) in the use per treatment for the leading ESRD drugs and aggregated them into four therapeutic

classes: erythropoiesis-stimulating agents (ESAs), iron agents, bone and mineral metabolism agents (including vitamin D agents and the two calcimimetics, cinacalcet and etelcalcetide), and other products.²⁴

As shown in Table 6-3, use of all ESRD-related drugs available between 2020 and 2021 declined except for darbepoetin alfa, biosimilar epoetin alfa (which was launched in late 2018), iron sucrose, cinacalcet, daptomycin, vancomycin, levocarnitine, and alteplase. With the inclusion of the two calcimimetics in the

FIGURE 6-3**Use of ESRD drugs paid under the ESRD PPS has declined**

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

*In 2020, calcimimetics were paid on a per unit basis under a transitional drug add-on payment policy. In 2021, calcimimetics were included in the ESRD PPS bundle and paid under the base rate.

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

ESRD PPS bundle in 2021, the use of oral cinacalcet (with brand-name and generic formulations) increased while the use of injectable etelcalcetide (with only brand-name formulations) decreased compared with 2020, when both products were paid on a per unit basis under an add-on payment to the ESRD PPS payment rate. Under the ESRD PPS, the Commission reported a shift over time in the use of products within the ESA and vitamin D therapeutic classes due to price competition among the products within each class (Medicare Payment Advisory Commission 2022).

As shown in Figure 6-3, most of the decline in the per treatment use of ESRD drugs occurred in the early years of the PPS. (We estimated per treatment use by multiplying drug units per treatment reported on CMS claims by each drug's 2021 ASP + 0 percent—i.e., holding price constant.²⁵) For example, between 2010 and 2011, use per treatment across all therapeutic classes declined by 23 percent. Most of this decrease was due to declining ESA use, which also fell by 23 percent per year during the same period. Some of the decline in ESA use may have stemmed from clinical

evidence showing that higher doses of these drugs led to increased risk of morbidity and mortality, which resulted in the FDA changing the ESA label in 2011.

Between 2020 and 2021, holding price constant, the use of all ESRD drugs in the four classes declined by 15 percent. Most of this decline was due to the lower use of etelcalcetide in 2021 (when it was included in the ESRD PPS bundle) compared with 2020 (when it was paid under a TDAPA). Excluding both calcimimetics from this analysis, the use of all ESRD drugs would have declined by 1 percent between 2020 and 2021. Although the ESRD PPS affected use of certain ESRD-related services, particularly the provision of drugs paid under the bundle, CMS has concluded that the agency's claims-based monitoring program has revealed no sustained negative changes in beneficiary health status (Centers for Medicare & Medicaid Services 2019).

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

Another measure of access is whether providers have a financial incentive to expand the number of Medicare beneficiaries they serve. In considering whether to treat a patient, a provider with excess capacity compares the revenue it will receive (i.e., the Medicare payment) with its marginal costs—that is, the costs that vary with volume. If Medicare payments are larger than the marginal costs of treating an additional beneficiary, a provider has a financial incentive to increase its volume of Medicare beneficiaries if it has the capacity to do so. In contrast, if payments do not cover the marginal costs, the provider could have a disincentive to care for Medicare beneficiaries.²⁶ In 2021, Medicare FFS accounted for about 47 percent of all treatments furnished by freestanding facilities.

For dialysis facilities in 2021, Medicare payments exceeded dialysis facilities' marginal costs by 20 percent, a positive indicator of patient access in that facilities with available capacity have a financial incentive to treat Medicare beneficiaries.

Quality of care is difficult to assess due to the effects of the coronavirus pandemic

Quality of care is challenging to interpret due to effects of the coronavirus pandemic on many of our measures. While we report 2021 quality results, we do not use them to assess any trends in the quality of

care, especially those that may reflect the adequacy of Medicare payments in 2021. Many factors related to the pandemic, including hospital capacity constraints and patient avoidance of health care settings, affected rates of hospitalizations.

In 2020 and 2021, FFS dialysis beneficiaries' use of the emergency department (ED) remained stable while rates of hospitalization and mortality increased slightly. Results of process measures that assess dialysis adequacy and anemia management (hemoglobin levels) remained generally stable, although blood transfusion rates increased between 2020 and 2021. Use of home dialysis and the number of kidney transplants increased during this period. The findings, except where indicated, are based on the Commission's analysis of Medicare FFS enrollment and claims data.

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 (see text box, pp. 186–187).

Quality under the ESRD PPS

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

- Between 2017 and 2019, mortality averaged between 1.5 percent per month to 1.6 percent per month, while in 2020 and 2021, the rate of mortality per month increased to 1.9 percent and 2.0 percent, respectively (Centers for Medicare & Medicaid Services 2019).
- Between 2017 and 2021, the share of FFS dialysis beneficiaries admitted to a short-stay hospital (beneficiaries with at least one admission in a given month) ranged from 12 percent per month to 14 percent per month. During the same period, 30-day readmission rates on an annual basis remained relatively steady at 22 percent of admissions.
- Between 2017 and 2019, the share of FFS dialysis beneficiaries who used the ED on an outpatient basis (beneficiaries with at least one ED visit in a given month) averaged 12 percent per month. In 2020 and 2021, ED use remained steady at 10 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 2017 and 2021, 98 percent of hemodialysis beneficiaries and 93 percent of PD beneficiaries received adequate dialysis.

We assess the quality of anemia management by examining changes over time in (1) beneficiaries' hemoglobin level, a blood test that measures the level of hemoglobin, the protein that carries oxygen in red blood, and (2) frequency of red blood cell transfusions.²⁷ Lower hemoglobin levels (which suggest underuse of ESAs and iron agents) can increase the frequency of red blood cell transfusions, while higher hemoglobin levels (greater than 12 g/dL) among patients maintained on higher doses of ESAs can increase their risk of death and cardiovascular events (congestive heart failure, myocardial infarction, and stroke).

Between 2017 and 2021, median hemoglobin levels have remained constant, averaging 10.5 g/dL. During this period, the share of FFS dialysis beneficiaries with lower hemoglobin levels (less than 10 g/dL) rose from 28 percent of beneficiaries to 31 percent of beneficiaries while the share of FFS beneficiaries with levels between 10g/dL and 12g/dL fell from 67 percent to 63 percent. During this period, the share of beneficiaries with higher hemoglobin levels (exceeding 12 g/dL) remained relatively constant, at about 5 percent of FFS dialysis beneficiaries.

We see fluctuation in another anemia management measure, rates of blood transfusion. Between 2017 and 2020, the proportion of FFS dialysis beneficiaries receiving a blood transfusion declined from an average of 2.7 percent per month to 2.4 percent per month. In 2021, the share of FFS dialysis beneficiaries receiving a blood transfusion increased to an average of 2.7 percent per month.

Access to home dialysis

Researchers have shown that the ESRD PPS is associated with an overall increase in the use of home dialysis (Lin et al. 2017). Between 2017 and 2021, the share of beneficiaries dialyzing at home steadily increased from 11 percent per month to nearly 15 percent per month. While we are encouraged by this

increase, differences by race persist: Black beneficiaries are less likely to use home methods. According to the Commission's analysis, about 33 percent of Medicare beneficiaries with ESRD are Black, but only 25 percent of beneficiaries who dialyze at home are Black. Between 2017 and 2021, the proportion of beneficiaries undergoing home dialysis training was relatively small but increased slightly, ranging from a monthly average of 0.7 percent to 0.9 percent of dialysis beneficiaries.

Researchers have identified many factors that affect the use of home dialysis, both clinical (patients' other health problems and prior nephrology care) and nonclinical (e.g., patients' social circumstances and knowledge about treatment options and physicians' training and preference). For example, nephrology trainees reported low and moderate levels of preparedness for managing patients on home hemodialysis and PD, respectively (Gupta et al. 2021). Some beneficiaries report that they were never informed about their options. Facility factors, such as unused in-center capacity or additional in-center shifts and dialysis facility staff experience, can also affect use of home dialysis (Walker et al. 2010). During the coronavirus pandemic, however, both LDOs and midsize providers reported that their patients showed increased awareness of and interest in home dialysis.²⁸

Some clinical and nonclinical factors affecting home dialysis use are amenable to intervention. For example, between 2008 and 2018, under an integrated care delivery system (Kaiser Permanente Northern California), PD use among new dialysis patients more than doubled, from 15 percent to 34 percent. To augment the use of home dialysis, the health care system implemented a multidisciplinary, system-wide approach that increased patient and family education, educated health care professionals about the importance of PD, adopted operational improvements, monitored outcomes, and shared best practices with staff (Pravoverov et al. 2019).

Access to kidney transplantation

Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical outcomes and quality of life. In addition, transplantation results in lower Medicare spending. In 2020, average Medicare spending for patients who had a functioning kidney transplant was

Medicare's efforts to improve management of late-stage chronic kidney disease and end-stage renal disease

The goals of care for patients with chronic kidney disease (CKD) are to delay progression to end-stage renal disease (ESRD), reduce complications, educate patients about their treatment options for ESRD, and ensure a timely transition to transplantation or dialysis while optimizing patients' independence (Levin et al. 2014). Here, we discuss models designed by the Center for Medicare & Medicaid Innovation (CMMI) that aim to improve the quality of care and lower Medicare spending for individuals with late-stage CKD and for individuals with ESRD. In addition to these CMMI models, Medicare links outpatient dialysis prospective payment system (PPS) payments to the quality of care that facilities provide under the ESRD Quality Incentive Program (QIP).

The Comprehensive ESRD Care Model, a specialty ACO, improved quality of ESRD care

The relatively high resource use by dialysis beneficiaries, particularly rates of hospital admissions and hospital readmissions, suggests that further improvements in quality are needed and that some dialysis beneficiaries might benefit from better care coordination. Results from CMMI's Comprehensive ESRD Care (CEC) Model, Medicare's first accountable care organization (ACO) model (a five-year shared savings program that ended in 2021) that targeted a particular clinical population, found that key quality metrics improved, with beneficiaries in the model having fewer hospitalizations due to

ESRD complications, fewer hospital readmissions, lower catheter use, and improved adherence to dialysis. The CEC Model reduced total Part A and Part B spending by an estimated \$217 million over the model's five performance years, primarily generated through a decrease in hospitalizations and readmissions. Specifically, the number of hospitalizations and the share of beneficiaries with at least one readmission decreased 3 percent and 2 percent across the five performance years, respectively (Marrufo et al. 2022). Although the CEC Model resulted in lower total Part A and Part B spending, Medicare experienced aggregate net losses after taking into account shared savings payments made to participants (Marrufo et al. 2022).

The ESRD Treatment Choices Model aims to promote home dialysis and kidney transplantation

CMMI's ESRD Treatment Choices (ETC) Model, which began in 2021, is a mandatory model that aims to promote home dialysis and kidney transplantation and applies to dialysis facilities and managing clinicians who furnish monthly capitated payment services. CMS chose participants according to their location in randomly selected geographic areas (hospital referral regions), stratified by region, to account for approximately 30 percent of adult dialysis beneficiaries. CMS adjusts participants' payment through two adjustments upward or downward based on their home dialysis and kidney

(continued next page)

substantially less than spending for dialysis patients (\$39,216 vs. \$94,460) (United States Renal Data System 2022). However, demand for kidney transplantation exceeds supply of available kidneys. Besides donation rates, factors that affect access to kidney transplantation include the clinical allocation process; patients' health literacy, clinical characteristics, and preferences; the availability of education for patients; clinician referral

for transplant evaluation at a transplant center; communication between the dialysis facility and the transplant center; and transplant center policies.

Between 2017 and 2021, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 6 percent per year, to 24,670 (Table 6-4, p. 188). The increase

Medicare's efforts to improve management of late-stage chronic kidney disease and end-stage renal disease (cont.)

transplant rates. Specifically, the first adjustment—the home dialysis payment adjustment—is applied during the initial three years of the model and increases a participating facility's adjusted PPS base payment rate for home dialysis treatments. The second adjustment—the performance payment adjustment—is applied beginning in year two through the end of the model and can either increase or decrease a participating facility's adjusted PPS base payment rate for home and in-center dialysis treatments. CMS estimated that the Medicare program would, on net, reduce Medicare spending by \$28 million over the ETC Model's six-year duration through decreased payments to dialysis facilities (Centers for Medicare & Medicaid Services 2021).

Kidney Care Choices Model aims to delay the initiation of dialysis and incentivize kidney transplantation

CMMI's Kidney Care Choices Model aims to delay the initiation of dialysis and incentivize kidney transplantation for fee-for-service (FFS) beneficiaries with chronic kidney disease stages 4 and 5 (not on dialysis), ESRD FFS beneficiaries on dialysis, and beneficiaries who were aligned to a participating provider due to CKD and ESRD who received a transplant. The model, which began in 2022 and spans five performance years, is based on benchmark and payment methodologies used in the Comprehensive ESRD Care Model, the

Direct Contracting Model, and the Primary Care First Model. The Kidney Care Choices Model tests whether these design elements will reduce Medicare spending and improve the quality and coordination of care for beneficiaries with late-stage CKD, ESRD, and kidney transplants.

Linking ESRD PPS payments to quality of care

Since 2012, outpatient dialysis payments under the ESRD PPS are linked to the quality of care that facilities provide under the ESRD QIP to promote high-quality services in renal dialysis facilities. Under statutory provisions, the maximum payment reduction that CMS can apply to any facility is 2 percent. For example, in 2021, the QIP assessed facility-level quality using clinical measures that assess dialysis adequacy, vascular access among hemodialysis beneficiaries, hospitalization rates, hospital readmission rates, blood transfusion rates, presence of hypercalcemia, bloodstream infections among hemodialysis beneficiaries, the number of dialysis patients on the transplant waiting list, and the quality of care that in-center hemodialysis beneficiaries report that they receive from their nephrologist and dialysis facility and process measures that assess whether dialysis facilities report on clinical depression screening, ultrafiltration rates, medication reconciliation, and infection events (reported to the Centers for Disease Control and Prevention's National Healthcare Safety Network). ■

was mostly due to an increase in the number of deceased donor transplants. During this period, the share of transplants for Black and Hispanic patients rose while the share of transplants for White patients fell (Table 6-4). According to researchers, a kidney allocation system implemented in 2014 by the United Network for Organ Sharing led to a narrowing of the disparities in national kidney transplant rates among

White, Black, and Hispanic patients on the transplant waiting list (Melanson et al. 2017). However, differences by race persist in living donor transplantation (Purnell et al. 2018). For example, data from the US Renal Data System show that rates of living donor transplantation are lower for Black and Hispanic dialysis patients than for White dialysis patients (United States Renal Data System 2022).²⁹

**TABLE
6-4**

Between 2020 and 2021, the number of kidney transplants increased

	2017	2020	2021
Total transplants	19,849	22,817	24,670
Share of transplants from live donors	29%	23%	24%
Share receiving a transplant			
White	47	45	42
Black	27	27	29
Hispanic	18	18	20
Asian	7	7	7
Other	2	2	2

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

Source: Organ Procurement and Transplantation Network.

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

Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients across all types of health coverage who require dialysis. The two LDOs as well as other renal companies appear to have had adequate access to capital. For example:

- In 2022, Fresenius Medical Care completed a three-way merger that includes Fresenius Health Partners (its value-based care division), InterWellHealth, and Cricket Health. The new company will focus on services for the care of individuals with earlier stages of kidney disease, will operate under the InterWell Health brand, and anticipates managing the care of roughly 300,000 individuals in the U.S. with kidney disease, with more than \$11 billion in costs under management by 2025 (Landi 2022).
- In December 2021, DaVita acquired a transplant software business, MedSleuth, that works with transplant centers across the U.S. to provide greater connectivity among transplant candidates, transplant centers, and physicians and care teams to help improve the experience and outcomes for kidney and liver transplant patients.
- In 2022, DaVita announced that it will form a kidney care-focused medical device company

with Medtronic that will specialize in developing novel kidney care products and solutions, including home-based products to make different dialysis treatments more accessible. The joint venture, NewCo, will be equally owned by both companies. Medtronic and DaVita will each provide approximately \$200 million in cash to launch NewCo. DaVita has agreed to pay Medtronic additional consideration if NewCo achieves a set of regulatory and commercial milestones. The transaction is expected to close in 2023, subject to regulatory approvals and closing conditions.

Another indicator of the relatively good access to capital is that, during the past decade, several companies—both small and large—have entered the renal care field aiming to improve treatment of individuals with CKD and ESRD, including Outset Medical (in 2010), Cricket Health (in 2015), Somatus (in 2016), and CVS (in 2018). Most recently, in 2021, Diality Inc., a medical device company that is developing a versatile hemodialysis system, announced the close of a \$12.5 million Series B investment round.

In public financial filings, the two LDOs reported generally positive financial performance related to their dialysis business for 2021, including improvements in productivity and revenue growth—that is, growth achieved apart from mergers and acquisitions. Since

2010, the two LDOs have also grown through large acquisitions of and mergers with other dialysis facilities and other health care organizations. For example, during this period, both of the largest dialysis organizations acquired midsize for-profit organizations: DaVita acquired Purity and Renal Ventures and Fresenius Medical Care acquired Liberty Dialysis.

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

Another positive indicator of the dialysis sector's strong access to capital is its all-payer margin. Using cost report data submitted by freestanding dialysis facilities to CMS, the 2021 all-payer margin was roughly 17 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. Although commercial payment rates vary, average rates established under commercial contracts are generally significantly higher than Medicare rates. According to one LDO, patients with commercial coverage (including hospital dialysis services) account for 10 percent of its treatments and about 32 percent of its U.S. dialysis patient revenues, while patients with government coverage account for 90 percent of its treatments and 68 percent of its U.S. dialysis patient revenues (DaVita 2022, DaVita 2018).

In general, current growth trends among dialysis providers indicate that the dialysis industry is attractive to for-profit facilities and investors.

Medicare payments and providers' costs: Increased costs in most cost categories contributed to slight decline in Medicare margins

In 2021, total Medicare spending for outpatient dialysis services dropped by 19 percent, due predominantly to a sharp decline in the number of FFS dialysis beneficiaries, as enrollment in MA plans by dialysis beneficiaries soared. Medicare's payment per FFS dialysis treatment increased 0.9 percent while total cost per treatment rose by 1.3 percent in 2021. Growth in many cost categories was offset by a 21 percent decline in ESRD drug costs, a consequence of the continued decline in ESA costs and the cessation of separate payments for calcimimetics, which were included in the ESRD payment bundle beginning in 2021. In 2021, the aggregate Medicare margin decreased slightly to 2.3 percent (2.7 percent including pandemic relief funds). We project that the aggregate Medicare margin for 2023 will be -0.4 percent, a conservative estimate, as it assumes a rate of provider cost growth for 2023 that is high relative to past experience and does not account for the potential effect of add-on payments for a new home dialysis machine and a new ESRD drug that began in 2022.

Medicare payments for outpatient dialysis services

In 2021, Medicare spending for outpatient dialysis services was \$10.0 billion, a 19 percent drop compared with 2020; per capita annual spending declined by 6 percent to roughly \$30,200. This decline is due in large part to the increasing enrollment of dialysis beneficiaries in MA plans between 2020 and 2021. Specifically, between 2020 and 2021, the annual number of FFS dialysis beneficiaries and treatments declined by 14 percent and 20 percent, respectively. In addition, the decline in spending could be linked to Medicare's inclusion of calcimimetics in the ESRD PPS bundle in 2021. Payment on a per unit basis under a TDAPA in 2020 did not likely promote their efficient prescription. A statutory update (of 1.6 percent) increased the base dialysis payment rate in 2021.

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. By contrast, CKD is usually caused by a long-term disease, such as hypertension or diabetes, that slowly damages the kidneys and reduces their function over time. AKI is more commonly reversible than late-stage CKD.

In 2021, Medicare spending for outpatient dialysis services for beneficiaries with AKI was nearly \$80 million, an increase from nearly \$77 million in 2020. Medicare pays facilities the ESRD PPS base rate adjusted by the PPS wage index for the treatment of beneficiaries with AKI.³⁰ Medicare spending for treatment of AKI by dialysis facilities is not included in the Commission's analysis of Medicare's payments and costs for dialysis facilities (including our Medicare margin analysis).

Between 2019 and 2020, Part D spending for ESRD oral-only phosphate binders declined

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; therefore, we track spending for this group. Between 2019 and 2020 (the most recent year for which data are available), spending for phosphate binders furnished to dialysis FFS beneficiaries declined by 1 percent to \$0.9 billion.³¹ In 2020, roughly 70 percent of FFS dialysis beneficiaries with Part D coverage were prescribed phosphate binders, and Part D spending for phosphate binders accounted for 36 percent of their Part D spending. Medicare spending for ESRD drugs under Part D is not included in the Commission's analysis of dialysis facilities' financial performance under the ESRD PPS.

As of January 1, 2025, phosphate binders covered under Part D will be included in the ESRD PPS bundled payment. Their inclusion is intended to lead to better management of drug therapy and improve beneficiaries' access to these medications since some beneficiaries lack Part D coverage or have coverage less generous than the Part D standard benefit. Including phosphate binders in the ESRD PPS bundle might also improve provider efficiency. For example, between 2019 and 2020:

- Medicare total spending increased for the phosphate binders that did not have generic competitors.
- Despite inconclusive evidence about whether calcium-free phosphate binders reduced

cardiovascular events compared with calcium-based agents, Part D spending for calcium-free agents has increased (Ogata et al. 2021). The appropriate use of calcium-based phosphate binders has the potential to reduce health care expenditures because of their low cost and high tolerability (Jovanovich 2020).

Providers' costs for outpatient dialysis services under the ESRD PPS

To assess the appropriateness of costs for dialysis services paid for under the ESRD PPS, we examine whether aggregate dialysis facility costs reflect costs that providers would incur in furnishing high-quality care. For this analysis, we used 2020 and 2021 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 total treatment volume affected that cost.

Cost growth under the ESRD PPS Between 2020 and 2021, total cost per treatment rose by 1.3 percent, from \$266 per treatment to nearly \$270 per treatment. This change results from a 21 percent decline in ESRD drug costs offset by an increase in the cost of:

- administrative and general expenses, which rose by 7 percent and accounted for 27 percent of cost per treatment in 2021;
- capital costs, which rose by 6 percent and accounted for 18 percent of cost per treatment in 2021;
- labor costs, which rose by 2 percent and accounted for 34 percent of cost per treatment in 2021; and
- supplies and labs, which rose by 2 percent and accounted for 13 percent of providers' cost per treatment in 2021.³²

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 2020 and 2021, per treatment costs fell by 4 percent for facilities in the 25th percentile of cost growth, compared with a rise of 6 percent for facilities in the 75th percentile. This finding is similar to our results from 2019 to 2020, in which per treatment costs fell by 5 percent for facilities in the 25th percentile, compared with a rise of 5 percent for facilities in the 75th percentile.

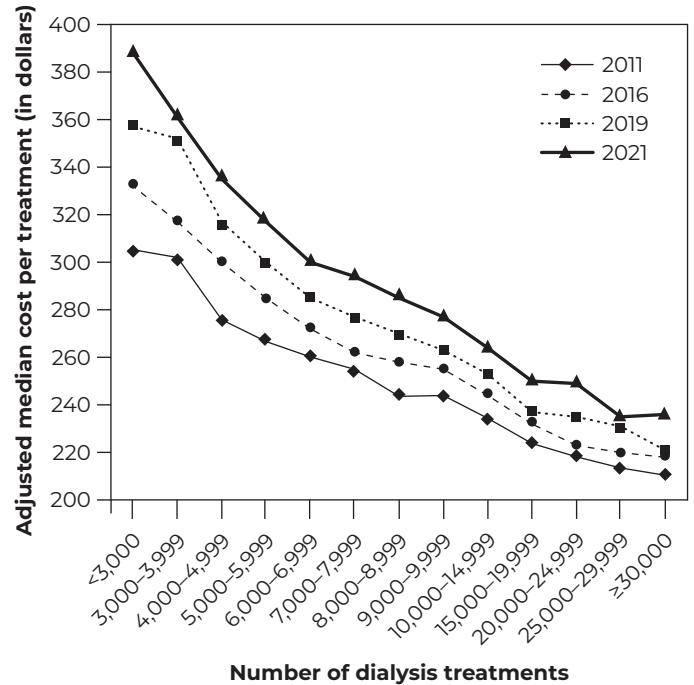
The extent to which some of the variation in costs among facilities results from differences in the accuracy of facilities' reported data is unknown. Under the ESRD PPS, we have found substantial variation in the level of selected cost categories reported by the five largest dialysis organizations. For example, in 2021, labor cost per treatment varied by \$44 per treatment, and capital costs varied by \$34 per treatment.

Consistent with our 2014 recommendation, the Protecting Access to Medicare Act of 2014 (PAMA) funded CMS to audit a representative sample of ESRD facility cost reports. It is basic fiscal management to ensure that facilities' cost reports are accurate. The agency published the results of their audit in the ESRD proposed rule for calendar year 2022. Because CMS did not publish total reported costs for the audited facilities or the share of total reported costs that were unallowable, we roughly estimated these values using 2018 cost reports submitted by freestanding facilities to CMS. Based on our analysis, we estimate that CMS's finding of \$147.5 million in unallowable costs represents about 4 percent of reported costs in 2018.³³ Our estimate assumes that audited facilities in the aggregate had average costs (i.e., audited facilities were assumed to be of average size, as measured by total treatments furnished); if the aggregate costs of audited facilities were lower or greater than the average, the estimated share of unallowable costs would be larger or smaller. If 4 percent of reported costs are unallowable, the estimated aggregate Medicare margin would be understated by nearly 4 percentage points.

Cost per treatment is correlated with facility service volume Cost per treatment is correlated with the total number of treatments a facility provides. To examine this relationship, we adjusted the cost per treatment to remove differences in the cost of labor across geographic areas and included all treatments regardless of payer. Our analysis showed, in each year from 2011 through 2021, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-4). 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.

FIGURE 6-4

Higher-volume dialysis facilities have lower cost per treatment, 2011-2021



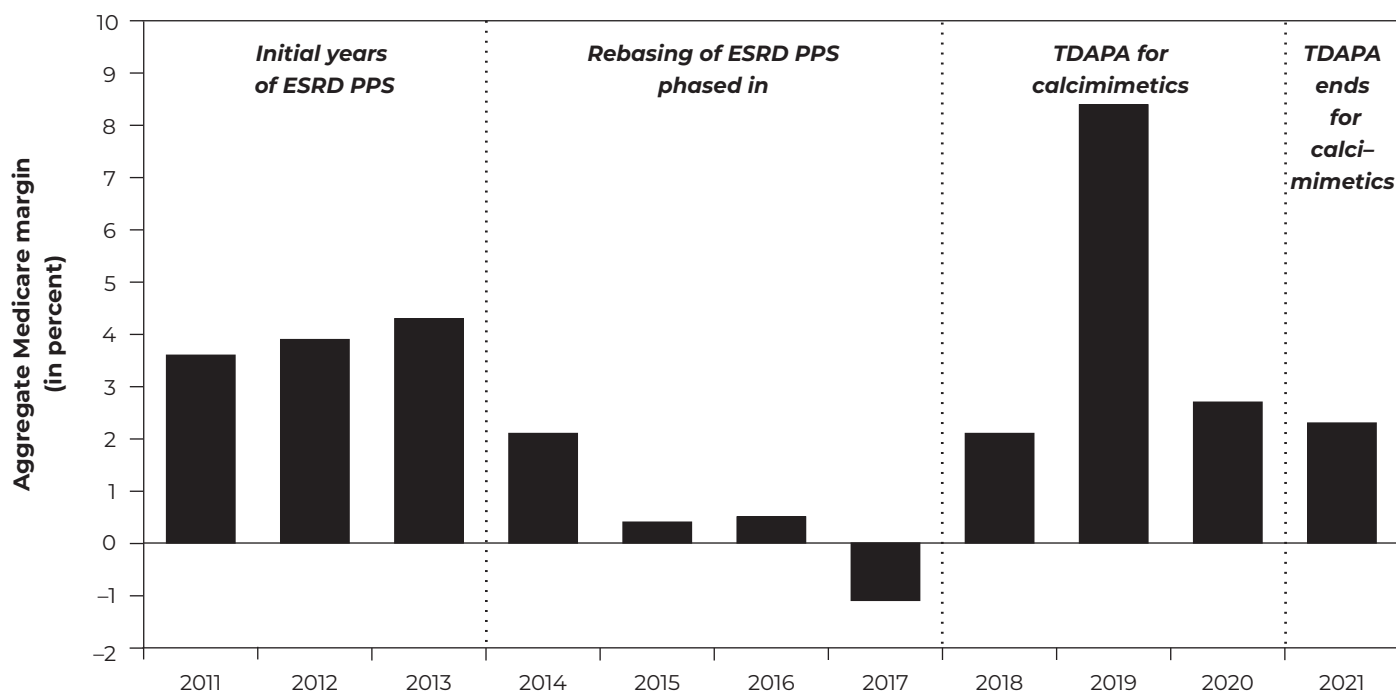
Note: Cost per treatment is adjusted to remove differences in the cost of labor. "Dialysis facilities" includes those paid by all insurance sources.

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

The trend in the aggregate Medicare margin for freestanding dialysis facilities

The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with facilities' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2021.

Under the ESRD PPS, dialysis facilities' financial performance under Medicare has varied due to statutory and regulatory changes and the use and profitability of certain ESRD-related drugs (Figure 6-5, p. 192). During the initial years of the ESRD PPS, the aggregate Medicare margin increased, particularly because of declining use of ESRD drugs between 2010

FIGURE 6-5**Aggregate Medicare margin changed in response to payment policies**

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

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

and 2012. Between 2014 and 2017, facilities' financial performance under Medicare reversed, with the aggregate Medicare margin declining from 2.1 percent to -1.1 percent, which was not unexpected given the payment adjustments required by statute. To reflect more current use of ESRD drugs, the American Taxpayer Relief Act of 2012 required that CMS rebase the base payment rate effective 2014, and PAMA set the statutory update at (1) 0 percent in 2015, (2) market basket minus 1.25 percent in 2016 and 2017, and (3) market basket minus 1.0 percent in 2018.³⁴

In 2018 and 2019, the aggregate Medicare margin increased due to the profitability of the calcimimetics paid under the TDAPA policy. The aggregate Medicare margin was 2.1 percent in 2018 and 8.4 percent in 2019 (Figure 6-5).³⁵ The increase in the aggregate Medicare margin between 2018 and 2019 is associated with 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).

In 2020, the aggregate Medicare margin decreased to 2.7 percent (Figure 6-5). This decline is linked to increasing cost per treatment and to the TDAPA payment declining from ASP + 6 to ASP + 0. We also

**TABLE
6-5**

In 2021, the aggregate Medicare margin of freestanding dialysis facilities varied by treatment volume

Provider type	Aggregate Medicare margin	Share of freestanding dialysis facilities	Share of freestanding dialysis facility treatments
All	2.3%	100%	100%
Urban	3.0	84	88
Rural	-1.4	16	12
Treatment volume (quintile)			
Lowest	-20.6	20	7
Second	-9.2	20	13
Third	-1.1	20	18
Fourth	4.5	20	24
Highest	10.3	20	39

Note: Pandemic-related federal relief funds are not included in the data presented in this table. Components may not sum to 100 percent due to rounding.

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

calculated an aggregate Medicare margin that includes a portion of the congressional pandemic relief funds (based on FFS Medicare’s share of 2019 all-payer operating revenue) because these funds were intended to help cover lost revenue and payroll costs—including lost revenue from Medicare patients and the cost of staff that help treat these patients. Including these funds raises the 2020 aggregate Medicare margin to 3.7 percent (data not shown).

In 2021, the aggregate Medicare margin decreased to 2.3 percent (Figure 6-5). This decline is attributable to increasing cost per treatment for all cost categories with the exception of ESRD drug costs. Including a portion of the congressional pandemic relief funds raises the 2021 aggregate Medicare margin to 2.7 percent (data not shown).

The aggregate Medicare margin varies by treatment volume

Aggregate Medicare margins in 2021 decidedly varied by treatment volume: Facilities in the lowest volume quintile had margins below -20 percent, while facilities

in the top volume quintile had margins of over 10 percent (Table 6-5). Urban facilities averaged higher margins than rural facilities (3.0 percent vs. -1.4 percent). Total treatment volume accounted for much of the difference in margins between urban and rural facilities. Urban dialysis facilities are larger on average than rural facilities in terms of the number of treatment stations and total treatments provided. For example, in 2021, urban facilities averaged about 11,000 treatments, while rural facilities averaged about 7,600 treatments (data not shown). And, as shown in Figure 6-4 (p. 191), higher-volume facilities had lower cost per treatment.

Although some rural facilities have benefited from the ESRD PPS’s 23.9 percent low-volume adjustment and 0.8 percent rural adjustment, the Commission has stated that neither adjustment targets low-volume, geographically isolated facilities that are critical to beneficiary access (Medicare Payment Advisory Commission 2016, Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014). The Commission’s recommendation to replace the current low-volume payment adjustment

and rural adjustment with a single low-volume and isolated adjustment, where low-volume criteria are empirically derived, would better protect isolated low-volume rural facilities that are necessary for beneficiary access (Medicare Payment Advisory Commission 2020).

Projecting the aggregate Medicare margin for 2023

We project that the aggregate Medicare margin for 2023 will be -0.4 percent, less than the 2021 Medicare margin (2.3 percent). This projection considers providers' historical cost growth and the policy changes that went into effect between 2021 (the year of our most recent margin estimates) and 2023, which include the following:

- In 2022 and 2023, the statutory dialysis base payment rate (based on the ESRD market basket offset by a productivity adjustment) increased by 1.9 percent and 3.0 percent, respectively.
- For 2023, CMS estimates that payments will be reduced by 0.38 percent due to the ESRD Quality Incentive Program.
- In 2023, CMS estimates that the ETC Model (CMMI's mandatory model) will decrease payments to facilities by \$3 million (Centers for Medicare & Medicaid Services 2021).

This projection is conservative since we assume a rate of provider cost growth for 2023 that is high relative to past experience. As a result, the Commission's projection assumes higher cost inflation than outpatient dialysis facilities are likely to experience, so margins in 2023 could be higher.

Additionally, we do not account for the effect of the new add-on payments for a home dialysis machine and a new ESRD drug that might improve providers' financial performance. Specifically, the projection does not account for the potential effect on providers' payments and costs of:

- The new transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) that CMS began to apply for a home dialysis machine in January 2022 for a two-year period. The technology will receive the TPNIES for two calendar years. CMS estimates that the TPNIES amount will equal \$24 per treatment (which is net

of an offset amount to account for the cost of home dialysis machines already in the PPS bundle).

- The new transitional add-on payment adjustment for a new drug (Korsuva), which began in April 2022 for a two-year period.

How should Medicare payments change in 2024?

The evidence suggests that Medicare's outpatient dialysis payments are adequate. It appears that facilities have become more efficient under the ESRD PPS, as measured by declining use of most injectable dialysis drugs, with little to no measurable impact on beneficiaries' health outcomes.

We note that, since 2020, in addition to the base payment rate, Medicare includes a TDAPA payment adjustment under the ESRD PPS that pays dialysis facilities for certain new drugs and biologics based on the product's ASP + 0 percent for a two-year period. If a drug becomes eligible for a TDAPA payment, this policy will likely increase Medicare payments relative to facilities' costs; CMS does not reconcile the cost and utilization of the new drug within an existing functional category with the cost and utilization of the drugs already included in the functional categories prior to the inclusion of the new drug.

Also since 2020, Medicare includes a payment adjustment under the ESRD PPS that pays dialysis facilities for new and innovative equipment and supplies based on the product's invoice price for a two-year period. For non-capital-related technologies, this policy could raise Medicare payments relative to facilities' costs because CMS will not offset the ESRD PPS base rate. (The payment adjustment for new and innovative home dialysis machines, a capital asset, includes an offset applied to the ESRD PPS base rate.)

Under current law, Medicare's base payment rate for outpatient dialysis services is increased annually based on the projected increase in the ESRD market basket less a projected increase in productivity. Although the final update for 2024 will not be set until later in 2023, CMS's current projections of the market basket and productivity would result in the base payment increasing by 1.8 percent.

RECOMMENDATION 6

For calendar year 2024, the Congress should update the 2023 Medicare end-stage renal disease prospective payment system base rate by the amount determined under current law.

RATIONALE 6

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, and access to capital. Providers have become more efficient in the use of dialysis drugs under the ESRD PPS. Indicators of quality of care have generally remained stable; for example, the use of home dialysis has increased and emergency department use has held steady. There was a modest increase in rates of admission and mortality between 2020 and 2021. The 20 percent marginal profit is a positive indicator of beneficiary access. The aggregate Medicare margin was 2.3 percent in 2021 and is projected to be -0.4 percent in 2023. Although we are uncertain about the effects of the TDAPA and TPNIES that CMS began in 2022 (for a two-year period) on providers' costs and Medicare payments, our prior analysis showed that the add-on payment for calcimimetics between 2018 and 2020 contributed to a substantial increase in provider profitability during this period.

Margins tend to be lower in low-volume and in rural dialysis facilities, in spite of the payment system's low-volume and rural adjustments, which increase payments by 23.9 percent and 0.8 percent, respectively. Previous Commission analyses have found that

neither adjustment appropriately targets low-volume, geographically isolated facilities. The Commission has stated that payments to rural providers should target facilities that are critical for beneficiary access (meaning facilities that are both low volume and isolated). Further, the magnitude of rural payment adjustments should be empirically derived, and the adjustments should encourage provider efficiency. In June 2020, the Commission recommended that the Secretary replace the current low-volume and rural payment adjustments with a single payment adjustment that considers both a facility's distance to the nearest facility and its treatment volume, thereby directing extra payments to the low-volume and isolated facilities that are most necessary for beneficiary access to care (Medicare Payment Advisory Commission 2020).

IMPLICATIONS 6

Spending

- In 2024, the statute sets the payment update at the market basket, net of the productivity adjustment. The Commission's recommendation would have no effect on federal program spending relative to the statutory update.

Beneficiary and provider

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

Endnotes

- 1 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to all individuals (across all types of health coverage) who have ESRD.
- 2 Throughout this chapter, we use the term *FFS Medicare* to mean the CMS term *Original Medicare*.
- 3 In this chapter, the term *drugs* refers to both drugs and biologics. The term *biologics* refers to biological products.
- 4 According to the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014, ESRD oral-only drugs cannot be paid under the ESRD PPS before January 1, 2025.
- 5 Medicare has been the main source of health care coverage for individuals with ESRD since the 1972 amendments to the Social Security Act that extended Medicare benefits to this population (Kirchhoff 2018). For individuals with ESRD to qualify for Medicare, including those under age 65, they must be fully or currently insured under the Social Security or Railroad Retirement program or be the spouse or dependent child of an eligible beneficiary.
- 6 There is a separate out-of-pocket threshold on Part D spending, which was \$7,050 in 2022, above which plan enrollees pay 5 percent of costs.
- 7 Under statutory provisions, states are not obligated to pay the full amount of Medicare cost sharing if the provider payment would exceed the state's Medicaid rate for the same service. States have the option to pay, for a given Medicare service received by a dually eligible beneficiary, the lesser of (1) the full amount of Medicare deductibles and coinsurance or (2) the amount by which Medicaid's rate for the same service exceeds what Medicare has already paid (this amount is zero in cases where Medicaid's rate is lower than Medicare's payment) (Medicaid and CHIP Payment and Access Commission 2015). However, under the ESRD PPS, Medicare reimburses dialysis facilities 65 percent of uncollected cost sharing, otherwise known as "bad debt."
- 8 Under the ESRD PPS, for pediatric dialysis beneficiaries (ages 17 years and under), the base rate is adjusted for age and type of dialysis.
- 9 The Commission's Payment Basics provides more information about Medicare's method of paying for outpatient dialysis services (see Outpatient Dialysis Services Payment System, available at https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_dialysis_FINAL_SEC.pdf).
- 10 The Commission's March 2014 report to the Congress provides more information about the rebasing of the dialysis base payment rate (available at http://medpac.gov/docs/default-source/reports/mar14_ch06.pdf?sfvrsn=0).
- 11 More information about these payment changes can be found in the Commission's March 2016 report to the Congress (available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-6-outpatient-dialysis-services-march-2016-report-.pdf). The Commission's methodological concerns about these patient-level and facility-level refinements can be found in our comment letter to CMS (available at <http://medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-.pdf?sfvrsn=0>).
- 12 In 2011, CMS delayed including ESRD oral-only drugs (calcimimetics and phosphate binders paid for under Part D) in the Part B ESRD prospective payment bundle to give facilities additional time to make operational changes and logistical arrangements to furnish these products to their beneficiaries. Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 delayed including oral-only renal dialysis services in the ESRD PPS bundled payment until January 1, 2025. According to CMS, these products are paid under a TDAPA because the base dialysis payment rate has not yet accounted for their costs.
- 13 In 2016, CMS established a drug designation process (as mandated by the Protecting Access to Medicare Act of 2014) for determining when ESRD oral-only drugs are no longer oral only and therefore must be paid under the ESRD PPS. Under the process, once the Food and Drug Administration approves an equivalent injectable product (or other non-oral forms), the agency pays facilities for both the oral and non-oral products under a TDAPA until sufficient claims data (at least two years' worth) for rate-setting analysis are available; thereafter, these drugs will be included in the PPS bundle.
- 14 Currently, drugs and biologics reported on dialysis facility claims are categorized into 1 of the following 11 functional categories: access management, anemia management, bone and mineral metabolism, cellular management, antiemetic, anti-infective, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management, and pain management.
- 15 New drugs ineligible for a TDAPA include generic drugs, which the 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); new drugs approved for a new formulation (e.g., new inactive ingredient); new drugs approved that were previously marketed without a new drug application (NDA); and new drugs approved that changed from prescription to over-the-counter availability. CMS will identify these drugs using the NDA classification code that the FDA assigns to an NDA.
- 16 The Commission recommended that the Congress direct the Secretary to eliminate the TDAPA for new drugs that are in an existing ESRD functional category that is already included in the payment bundle (Medicare Payment Advisory Commission 2020). Doing so would maintain the structure of the ESRD PPS and avoid the introduction of incentives to unbundle services covered under the PPS. Eliminating the TDAPA for these drugs would create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs.
 - 17 CMS defines a capital-related asset as an asset that a provider has an economic interest in through ownership (as set forth in the Provider Reimbursement Manual, Chapter 1, Section 104.1). The agency includes the following items as examples of capital-related assets: dialysis machines, water purification systems, and systems designed to clean dialysis filters for reuse.
 - 18 Because home dialysis machines are capital-related depreciable assets, CMS (1) applies a five-year straight-line depreciation method to determine an annual allowance, by dividing the Medicare administrative contractors-determined price by its useful life of five years; (2) divides the annual allowance by the number of treatments expected to be furnished in a year; and (3) reduces the payment by an offset that is intended to represent the portion of payment attributable to home dialysis machines from the base rate.
 - 19 According to the large dialysis organization (LDOs), during the coronavirus pandemic, interest in home dialysis increased among their patients. One LDO (Fresenius Medical Care) reported a rise in home dialysis trainings in 2020 compared with 2019 (Charnow 2020). In addition, the coronavirus pandemic-related restrictions may have affected the development of new facilities by dialysis organizations (Medicare Payment Advisory Commission 2022).
 - 20 Beginning in 2021, the ETC Model applies to certain dialysis facilities and managing clinicians who furnish monthly capitated payment services. CMS selected participants according to their location in randomly selected geographic areas (hospital referral regions), stratified by region, to account for approximately 30 percent of adult dialysis beneficiaries. CMS adjusts participants' payment upward or downward based on their home dialysis and kidney transplant rates. CMS estimated that the Medicare program would, on net, save \$28 million over the ETC Model's six-year duration through decreased payments to dialysis facilities.
 - 21 This figure is based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.
 - 22 Some portion of the decline in 2021 in the number of FFS dialysis beneficiaries and treatments may also have been due to the ongoing effects of the coronavirus pandemic. According to one of the LDOs, the overall number of patients that the company treated in 2021 fell by about 0.5 percent from 2020, primarily due to an increase in mortality rates because of the coronavirus pandemic. These rates were partially offset by patients starting dialysis (DaVita 2022).
 - 23 For example, researchers have reported that all-cause mortality among dialysis patients is significantly higher in winter compared with other seasons.
 - 24 These drug classes accounted for nearly all ESRD drug spending (about 97 percent) in 2010, the year before the start of the new payment method.
 - 25 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 2021 ASP, with one exception. Because 2021 ASP data were not available for cinacalcet, we used CMS's TDAPA payment limit for the fourth quarter of 2020. By holding the price constant, we account for the different billing units assigned to a given drug.
 - 26 If we approximate marginal cost as total Medicare costs minus fixed building and equipment costs, then marginal profit can be calculated as follows: $\text{Marginal profit} = (\text{payments for Medicare services} - (\text{total Medicare costs} - \text{fixed building and equipment costs})) / \text{Medicare payments}$. This comparison is a lower bound on the marginal profit because we do not consider any potential labor costs that are fixed.
 - 27 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.

- 28 See our March 2020 report to the Congress for more information on the factors that affect use of home dialysis and the factors associated with some patients' discontinuation of home dialysis (available at http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch6_sec.pdf?sfvrsn=0).
- 29 In 2020 (the most recent year for which data are available), the rate of living donor transplants per 100 dialysis patient-years was 1.3, 0.3, 0.6, and 0.9 for White, Black, Hispanic, and Asian dialysis patients, respectively (United States Renal Data System 2022).
- 30 In addition, for beneficiaries with AKI, Medicare pays dialysis facilities separately for drugs, biologics, and laboratory services that are not renal dialysis services.
- 31 Between 2017 and 2019, the FDA approved generic versions of several types of phosphate binders (including lanthanum, sevelamer carbonate, and sevelamer hydrochloride).
- 32 In 2020, ESRD drug cost per treatment accounted for 11 percent of total cost while all other components (capital, labor, supplies, labs, and administrative and general expenses) accounted for the remainder. In 2021, ESRD drug cost per treatment declined to 8 percent of total cost.
- 33 To determine total reported costs for audited facilities (which CMS did not publish in regulation), we multiplied 2018 average total costs per facility (derived from the 2018 freestanding cost reports) by 1,395 (the number of facilities that CMS audited). The share of reported costs that is unallowable is calculated by dividing \$147.5 million (CMS's finding of total costs that were unallowable) by our estimate of 2018 total costs for the 1,395 facilities that the agency audited.
- 34 As a result of rebasing, in 2014, CMS reduced the base payment rate by \$8.16 to \$239.02.
- 35 In 2019, there was an anomalous increase compared with prior years in non-ESRD-related drug costs for facilities associated with a dialysis organization.

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