

C H A P T E R

6

Outpatient dialysis services

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

- 6** For calendar year 2023, the Congress should update the 2022 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 2020, nearly 384,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from nearly 7,800 dialysis facilities. Since 2011, Medicare has paid for outpatient dialysis services based on a prospective payment system (PPS) bundle that includes certain dialysis drugs and ESRD-related clinical laboratory tests that were previously paid separately. In 2020, Medicare expenditures for outpatient dialysis services totaled \$12.3 billion. Six percent of the total consisted of payments for two calcimimetics paid under the ESRD PPS's transitional drug add-on payment adjustment (TDAPA); this policy pays providers according to the number of units of a drug and the drug's average sales price.

In this chapter, we recommend a payment rate update for 2023. Because of standard data lags, the most recent complete data we have for most payment adequacy indicators is from 2020. Where relevant, we have considered the effects of the 2020 coronavirus public health emergency (PHE) on our indicators and whether those effects are likely to be temporary or permanent. To the extent that the effects of the PHE are temporary or vary significantly across outpatient dialysis facilities, they are best addressed through targeted temporary funding policies rather

In this chapter

- Are Medicare payments adequate in 2022?
- How should Medicare payments change in 2023?

than a permanent change to all dialysis facilities' payment rates in 2023 and future years.

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 2015 and 2019, the number of in-center treatment stations grew faster than the number of FFS dialysis beneficiaries (but kept pace with demand from all dialysis patients across all types of health coverage). Between 2019 and 2020, capacity continued to grow but at a slower rate than between 2015 and 2019.
- **Volume of services**—Tragically, patients with ESRD are at increased risk for COVID-19–associated morbidity and mortality. Between 2019 and 2020, the number of FFS dialysis beneficiaries and the total number of treatments each declined by 3 percent. This decline is largely attributable to the coronavirus pandemic, which resulted in slowing the initiation of dialysis by new patients and in excess mortality. At the same time, use of ESRD drugs in the payment bundle (including erythropoiesis-stimulating agents (ESAs), which are used in anemia management) continued to decline, but at a slower rate than during the initial years of the ESRD PPS (2011 and 2012). The ESRD PPS created an incentive for providers to be more judicious about their provision of ESRD drugs that are included in the payment bundle.
- **The marginal profit**—An estimated 20 percent marginal profit in 2020 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries.

Quality of care—The growing trend under the ESRD PPS toward home dialysis, which is associated with better patient satisfaction, continued in 2020. Between 2019 and 2020, all-cause hospitalizations, emergency department use, and kidney transplantation declined while mortality increased. Each of these changes are likely linked to the pandemic. By contrast, between 2018 and 2019, kidney transplantation increased while the other quality metrics held steady.

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—Our analysis of Medicare payments and costs is based on 2019 and 2020 claims and cost report data submitted to CMS by freestanding dialysis facilities, which provided 96 percent of FFS dialysis treatments in both years. During this period, cost per treatment rose by 4 percent, while Medicare payment per treatment declined by 2 percent, and the aggregate Medicare margin fell from 8.4 percent to 2.7 percent. The decrease in the aggregate Medicare margin is linked to (1) a rise in the cost per treatment for all cost categories with the exception of ESAs and labs and (2) a drop in the TDAPA payment from average sales price (ASP) + 6 percent to ASP + 0 percent in 2020. Including provider-relief pandemic revenues, the aggregate Medicare margin was 3.7 percent.

While the PHE has made 2020 and 2021 anomalous years in many respects and it is impossible to predict with certainty the extent to which these effects will continue into 2022 and beyond, we project that the 2022 aggregate Medicare margin will drop to 1.8 percent, in part due to cost changes that will exceed payment updates. The projection reflects full sequester relief through March 2022 and 1 percent relief beginning April 2022 through June 2022.

How should Medicare payment rates change in 2023?

Under current law, the Medicare FFS base payment rate for dialysis services is projected to increase by 1.2 percent. Given that most of our indicators of payment adequacy are positive, the update recommendation is that for 2023, the Congress should 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. For each of these two dialysis types, patients may select various protocols.

Most dialysis patients travel to a treatment facility to undergo hemodialysis three times per week, although patients can also undergo hemodialysis at home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Because of recent clinical findings, there is increased interest in more frequent hemodialysis, administered five or more times per week while the patient sleeps, and short (two to three hours per treatment) daily dialysis administered during the day. Research has also increased interest in the use of “every-other-day” hemodialysis; reducing the two-day gap in thrice-weekly hemodialysis could be linked to improved outcomes.

PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed

independently in the patient's home or workplace five to seven days a week. During treatments, a cleansing fluid (dialysate) is infused into the patient's abdomen through a catheter. This infusion process (an exchange) is done either manually (continuous ambulatory peritoneal dialysis) or using a machine (automated peritoneal dialysis).

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. The use of home dialysis has grown since 2009, a trend that has continued under the dialysis PPS. 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 dialysis drugs and biologics to treat conditions such as anemia and bone disease resulting from the loss of kidney function.¹

The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD, including those under age 65. For individuals with ESRD to qualify for Medicare, 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.

In 2020, nearly 384,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from roughly 7,800 dialysis facilities.^{2,3}

Since 2011, Medicare has been paying facilities using a prospective payment system (PPS) bundle that includes dialysis drugs (for which facilities previously received separate payments) and services for which other Medicare providers (such as clinical laboratories) previously received separate payments.⁴ In 2020, Part B spending for Medicare-covered outpatient dialysis services was \$12.3 billion. This total includes payments of nearly \$712 million paid for the two ESRD drugs classified as calcimimetics—Sensipar (oral cinacalcet) and Parsabiv (injectable etelcalcetide)—that qualified, beginning in 2018, for a transitional drug add-on payment adjustment (TDAPA) under the ESRD PPS. Beginning in 2021, calcimimetics are included in the PPS bundle. Additionally, in 2019 (the most recent data available), Part D payments for ESRD oral-only drugs that were not yet included in the PPS—multiple phosphate binders—totaled nearly \$0.9 billion.⁵ A home dialysis machine qualifies, beginning in January 2022, for a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS for two calendar years and, beginning in April 2022, a drug (Korsuva) qualifies for a TDAPA.

In 2020, a majority of Medicare’s dialysis beneficiaries had FFS coverage. Historically, beneficiaries with ESRD were prohibited from enrolling in Medicare Advantage (MA) plans. However, beneficiaries enrolled in a managed care plan before receiving an ESRD diagnosis can remain in the plan after they are diagnosed (Medicare Payment Advisory Commission 2000). The 21st Century Cures Act allows ESRD beneficiaries to enroll in MA as of 2021. In addition, dialysis beneficiaries residing in selected geographic areas have access to ESRD special needs plans (SNPs) (specifically, in C-SNPs, a type of SNP for individuals with chronic conditions). As of October 2021, few dialysis beneficiaries—about 4,600—were enrolled in 10 ESRD SNPs operated by 6 managed care organizations in 5 states (Arizona, California, Connecticut, New Jersey, and Texas). Over time, the share of all Medicare ESRD beneficiaries on dialysis under FFS has gradually declined, while the share of beneficiaries enrolled in MA plans has increased. For example, between 2015 and 2020, the share of dialysis beneficiaries in MA rose from about 17 percent to 27 percent, while the share of dialysis beneficiaries in FFS fell from about 83 percent to 73 percent.

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, results from the first four performance years of the Center for Medicare & Medicaid Innovation’s (CMMI’s) Comprehensive ESRD Care (CEC) Model, Medicare’s first ACO model (a shared savings program that ended in 2021) targeted a particular clinical population, found that key quality metrics improved, such as fewer hospitalizations due to ESRD complications, fewer hospital readmissions, lower catheter use, and improved adherence to dialysis. 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. 2021). 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, 2020

Compared with all other Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately younger, male, and Black (Table 6-1). In 2020, 76 percent of FFS dialysis beneficiaries were less than 75 years old, 57 percent were male, and 35 percent were Black. By comparison, among all other FFS Medicare beneficiaries, 63 percent were less than 75 years old, 47 percent were male, and 11 percent were Black. A greater share of dialysis beneficiaries resided in urban areas compared with all other FFS beneficiaries (83 percent vs. 80 percent).

FFS dialysis beneficiaries are more likely to be dually eligible for Medicare and Medicaid than all other FFS beneficiaries (51 percent vs. 16 percent). In addition, in 2019 (the most recent data available), FFS dialysis beneficiaries were less likely to have coverage from

**TABLE
6-1****FFS dialysis beneficiaries are disproportionately young, male, and Black compared with all other Medicare FFS beneficiaries, 2020****Share of FFS beneficiaries:**

	Dialysis beneficiaries	All other beneficiaries
Age		
Under 45 years	10%	3%
45–64 years	37	10
65–74 years	29	51
75–84 years	18	26
85+ years	6	10
Sex		
Male	57	47
Female	43	53
Race		
White	46	81
Black	35	9
Hispanic	8	3
Asian	4	2
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	4
Frontier	1	1

Note: FFS (fee-for-service). “All others” excludes beneficiaries on dialysis and those who have received a kidney transplant. Beneficiary location reflects the beneficiary’s county of residence in one of four categories (urban, micropolitan, rural adjacent to urban, and rural not adjacent 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.

other sources, such as Medigap and employer-sponsored health plans (30 percent vs. 58 percent) and as likely to have no supplemental coverage (about 24 percent for each group in 2019). Since 1997, the American Kidney Fund has maintained a Health Insurance Premium Program that helps pay dialysis patients’ health insurance premiums, including Medicare Part B premiums.⁶

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 2009 and 2019 (the most recent year of data available), the adjusted incidence rate decreased by 1 percent per year, from 421 per million people to 386 per million

Kidney Care Choices Model aims to delay the progression of kidney disease and promote kidney transplants

CMMI's Kidney Care Choices Model aims to delay the initiation of dialysis and incentivize kidney transplantation for FFS beneficiaries with chronic kidney disease (CKD) 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.

The Kidney Care First (KCF) Option is open only to nephrologists and nephrology practices. Participants receive capitated monthly and quarterly payments for managing the care of aligned beneficiaries, adjusted upward or downward on the basis of health outcomes and utilization compared with both the participants' own experience and national standards, and performance on quality measures. In addition, KCF practices receive a bonus payment for every aligned beneficiary who receives a kidney transplant.

In contrast to the KCF Option, under the three Comprehensive Kidney Care Contracting (CKCC) Options, nephrologists and nephrology practices must partner with transplant providers and may also partner with dialysis facilities (and other providers and suppliers) to form Kidney Care Entities (KCEs). Participants receive monthly and quarterly capitated

(continued next page)

people, an increase of 1 percent compared with 2018 (United States Renal Data System 2021a).

In 2020, we estimate that the number FFS beneficiaries beginning dialysis declined by roughly 10,000 compared with 2018 and 2019. Specifically, in 2018 and 2019, about 83,000 beneficiaries were new to dialysis in each year, while in 2020, nearly 73,000 FFS beneficiaries were new to dialysis, with about half (45 percent) under age 65 and thus entitled to Medicare based on ESRD benefit rules (with or without disability).⁷ This decline is largely attributable to the coronavirus pandemic, which resulted in slowing the initiation of dialysis by new patients across all insurance types:

- According to the two largest dialysis providers, in 2020, the number of new dialysis starts declined.
- Data from the United States Renal Data System (USRDS) show that during the first six months

of 2020, the number of incident ESRD (dialysis and transplant) patients declined by 10 percent compared with the same period in 2019 (United States Renal Data System 2021b).

- Findings from researchers show that the number of patients with incident kidney failure initiating treatment in the first four months of 2020 substantially declined (particularly for Black patients and people living in counties with high COVID-19 mortality rates) compared with 2018 through 2019 (Nguyen et al. 2021).

The timing of starting dialysis is a matter of clinical judgment, guided by residual kidney function values and the symptoms and comorbidities of affected patients. From the mid-1990s through 2010, the Commission's analysis of data (from CMS's ESRD Medical Evidence Report) suggests a trend toward initiating dialysis earlier in the course of CKD. The proportion of new dialysis patients (of all types of

Kidney Care Choices Model aims to delay the progression of kidney disease and promote kidney transplants (cont.)

care management payments as well as the kidney transplant bonus payment. In addition, each of the three CKCC Options has its own accountability framework for the total cost and quality of care for its aligned beneficiaries:

- **CKCC Graduated Option:** KCEs can elect either one-sided risk in the first payment year (referred to as Level 1 of the Graduated Option) or two-sided risk with subsequent downside risk (referred to as Level 2 of the Graduated Option).⁸ KCEs selecting Level 1 for their first performance year automatically graduate to Level 2 for their second performance year. In addition, KCEs automatically transition into the CKCC Professional Option for each subsequent performance year after participation in Level 2 of the Graduated Option.

- **CKCC Professional Option:** Participants have an opportunity to earn 50 percent of shared savings or be liable for 50 percent of shared losses based on the total cost of care for Part A and Part B services.

- **CKCC Global Option:** Participants are at risk for 100 percent of the total cost of care for all Part A and Part B services for aligned beneficiaries.

KCEs are able to move from a lower-risk option to a higher-risk option at the start of each performance year but are not able to move to a lower-risk option from a higher-risk option. According to CMS, 30 KCF practices and 55 KCEs are participating in performance year 2022 of the KCC Model. ■

health coverage) with higher levels of residual kidney function steadily increased between 1996 and 2010, from 13 percent to nearly 44 percent. (An estimated glomerular filtration rate (eGFR)—a measure of residual kidney function—above 10 mL/min/1.73 m² is considered a higher level of residual kidney function. Lower values of this measure suggest comparatively less residual kidney function.)

While the share of patients initiating dialysis earlier in the course of CKD decreased modestly between 2011 and 2019 (from 43 percent to 40 percent), the share remains three times higher than in 1996. Researchers have questioned this early initiation of dialysis in those with late-stage CKD, concluding that it is not associated with improved survival or clinical outcomes (Cooper et al. 2010, Evans et al. 2011, Kazmi et al. 2005, Stel et al. 2009, Traynor et al. 2002). Of the few randomized controlled trials (RCTs) on this topic, the most influential RCT found that survival is similar between patients for whom dialysis is initiated

early (with an eGFR equal to 10.0 mL/min/1.73 m² to 14.0 mL/min/1.73 m²) and those for whom dialysis is electively delayed (with an eGFR equal to 5.0 mL/min/1.73 m² to 7.0 mL/min/1.73 m²) and concluded that dialysis can be delayed for some patients until the eGFR drops below 7.0 mL/min/1.73 m² or until more traditional clinical indicators for the initiation of dialysis are present (Cooper et al. 2010). Since publication of this RCT in 2010, the share of early dialysis initiation has begun to level off, but it has not yet returned to its earlier levels.

The goals of CMMI's Kidney Care Choices Model include delaying the initiation of dialysis and incentivizing kidney transplantation both for ESRD FFS beneficiaries on dialysis and for FFS beneficiaries with chronic kidney disease (CKD) stages 4 and 5 (not on dialysis). The text box describes the four payment options that this voluntary model offers participants beginning in 2022.

Better primary care management of the risk factors for CKD—particularly hypertension and diabetes, which together are the primary causes of roughly 7 of 10 new ESRD cases—can help prevent or delay the illness’s onset. Payers and dialysis providers are testing interventions among CKD patients to improve their clinical outcomes (e.g., reduced hospitalizations), prevent or slow kidney disease progression, and increase their preparedness for ESRD (e.g., by educating patients about treatment alternatives, including transplantation and home dialysis). Increasing the preparedness of CKD patients for ESRD may reduce the substantial morbidity, mortality, and costs associated with ESRD. For example, according to USRDS, receipt of pre-ESRD nephrology care was associated with greater use of the recommended type of vascular access—an arteriovenous fistula (United States Renal Data System 2020). In addition to the CMMI kidney models, some dialysis providers have entered into agreements with commercial payers to provide care coordination to individuals with CKD and ESRD. The Commission has long argued that primary care services are undervalued in Medicare’s fee schedule and has made recommendations to support primary care, which in turn could support better management of kidney disease risk factors.

Since 2011, Medicare has paid 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 (MCP) established in the Part B physician fee schedule for outpatient dialysis-related management services (which includes managing the dialysis prescription and prescribing dialysis 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.⁹ 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.

CMMI’s model—the ESRD Treatment Choices (ETC) Model (a mandatory model that aims to promote home dialysis and kidney transplantation and began in 2021)—acknowledges the need for collaboration. The ETC Model applies to dialysis facilities and managing clinicians who furnish MCP 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 through two adjustments upward or downward based on their home dialysis and kidney 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 and 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).¹⁰

To improve provider efficiency, in 2011 Medicare began a PPS for outpatient dialysis services that expanded the prospective payment bundle to add (1) Part B dialysis 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. 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 (18 years or older), 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).¹¹ 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.¹²

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 dialysis drug use under the ESRD PPS.¹³ 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.¹⁴ In addition, in 2018, 2019, and 2020, transitional add-on payments were used to pay for certain drugs (calcimimetics) and are 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).^{15,16} 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.¹⁷ (Functional categories are similar to therapeutic classes of drugs. Functional categories are based on physiologic end-point action, including products used for anemia,

bone and mineral metabolism, and antipruritic management). For these new drugs that do not fall within an existing functional category, in order to be considered a renal dialysis service, CMS will propose a new functional category through notice-and-comment rulemaking. Once the agency finalizes the new category, the drug is eligible for receipt of TDAPA that is paid based on its average sales price (ASP) for two years, and if appropriate changes may be made to the ESRD PPS base rate.

- **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, it 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.¹⁸ As of April 2022, CMS will pay a TDAPA for Korsuva (in the anti-pruritic functional category) for a two-year period.¹⁹
- **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, it is included in the PPS payment bundle without any change to the ESRD PPS base rate. Unlike ESRD drugs, a substantial clinical improvement standard is used to determine eligibility under this transitional payment policy.²⁰ CMS sets the new item's payment rate at 65 percent of the price that the Medicare administrative contractors (MACs) establish.²¹

Linking payments to quality of care

Since 2012, outpatient dialysis payments are linked to the quality of care that facilities provide under the ESRD Quality Incentive Program (QIP). Under statutory provisions, the maximum payment reduction that CMS

can apply to any facility is 2 percent. 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).

In 2021, of the roughly 7,300 facilities with a QIP performance score, 60 percent had no payment reduction, 22 percent had their Medicare outpatient dialysis payments reduced by 0.5 percent, 13 percent had payments reduced by 1.0 percent, 4 percent of facilities had payments reduced by 1.5 percent, and 2 percent of facilities had payments reduced by the maximum, 2.0 percent (total number of facilities does not sum to 100 percent due to rounding).

Are Medicare payments adequate in 2022?

To address whether payments for 2022 are adequate to cover the costs that efficient providers incur and how much providers' costs are likely to change in the update year (2023), 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.

While it is impossible to predict the future with any certainty, given the evolving coronavirus pandemic, we anticipate that most dialysis payment adequacy

indicators will remain positive in 2021. (For a description of how the coronavirus pandemic has been incorporated into our payment adequacy framework, see text box, pp. 206–207).

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 kept pace with dialysis patient demand across all insurance types

Growth in the number of dialysis facilities and in-center treatment stations alongside growth in dialysis beneficiaries suggests that, between 2015 and 2019, 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 4 percent annually (Table 6-2), compared with 0.4 percent annual growth in the number of FFS dialysis beneficiaries (data not shown). However, in-center capacity is growing to keep pace with demand from all dialysis patients, across all insurance types, not just FFS beneficiaries. During the most recent five-year period for which data are available (2014 to 2019), the number of dialysis patients of all types of health coverage grew 3 percent per year (data not shown) (United States Renal Data System 2021a).

The number of facilities' in-center treatment stations grew more slowly annually between 2019 and 2020 compared with growth from 2015 through 2019 (1 percent per year vs. 4 percent per year). The recent decline in the growth of in-center capacity may be partly attributable to a number of factors, including (1) coronavirus pandemic-related restrictions that may have affected the development of new facilities by dialysis organizations in 2020 and (2) CMMI's ETC Model, which CMS proposed in 2019 and implemented January 1, 2021. The model's financial incentives—rewards for increasing home dialysis use and kidney transplantation among adult ESRD beneficiaries and penalties for not increasing these outcomes—might have spurred providers and clinicians to recommend

**TABLE
6-2****Increasing number and capacity of freestanding, for-profit, and largest dialysis organizations**

	2020				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	
					2015–2019	2019–2020	2015–2019	2019–2020
All	44.3	7,800	135,900	18	4%	1%	4%	1%
Share of total								
Freestanding	96%	95%	96%	18	4	2	4	1
Hospital based	4	5	4	14	–3	–2	–3	–2
Urban	86	84	86	18	5	2	4	2
Micropolitan	10	10	9	16	2	–1	2	–1
Rural, adjacent to urban	3	4	3	14	2	–3	2	–2
Rural, not adjacent to urban	1	2	1	12	0.4	–2	1	–0.5
Frontier	0.2	0.4	0.2	10	1	–3	1	–2
For profit	89	89	89	18	4	2	4	1
Nonprofit	11	11	11	17	2	–1	2	–1
Two largest dialysis organizations	76	75	76	18	5	2	5	2
All others	24	25	24	17	1	–1	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 not adjacent 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. The number of treatment stations is imputed for nearly 200 facilities.

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

home dialysis more often. 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).

Between 2019 and 2020, capacity at both freestanding and for-profit facilities each grew by 1 percent per year, while capacity at hospital-based facilities decreased by 2 percent, and capacity at nonprofit facilities decreased by 1 percent per year. During this period, capacity at urban facilities grew 2 percent per year, while capacity

at all rural facilities declined by 1 percent per year (data for rural facilities are not aggregated). 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 ensure beneficiary access. The Commission found that the facilities that would receive the LVI adjustment would be more appropriately targeted compared

The coronavirus public health emergency and the Commission's assessment of payment adequacy for outpatient dialysis services

The coronavirus pandemic and associated public health emergency (PHE) had tragic effects on beneficiaries' health in 2020.²²

According to the Centers for Disease Control and Prevention (CDC), dialysis patients are at high risk for serious illness and death related to infection with COVID-19. According to CMS, between January 2020 and August 2020, beneficiaries eligible for Medicare due to end-stage renal disease (ESRD) had greater rates of COVID-19 cases and COVID-19 hospitalizations compared with beneficiaries who were eligible for Medicare due to age or disability. In-center capacity and the number of dialysis treatments furnished have increased but more slowly than in 2019. Treatment growth has been affected by increased mortality during the PHE and new patients delaying the start of dialysis, offset by a decline in patients undergoing kidney transplantation and dialysis beneficiaries enrolled in Medicare Advantage. The impact of the pandemic has varied considerably both geographically and over time, and it is not clear when or if the pandemic's full effects will end.

As discussed further in this chapter, the effects of the PHE on indicators of Medicare's payment adequacy to ESRD dialysis facilities include the following:

- Between 2019 and 2020, fee-for-service (FFS) treatment volume declined by 3 percent, owing to the 3 percent decline in number of FFS dialysis beneficiaries. Our analyses show that in 2020 there were fewer new FFS dialysis beneficiaries and higher mortality compared with 2019.
- In public statements, the large dialysis organizations (LDOs) (Fresenius Medical Care and DaVita) have said that mortality has increased among their patients, particularly the elderly. According to the CDC, over a 7-month period during the early months of the COVID-19 pandemic (February 2020 through August 2020), an estimated 6,953 to 10,316 excess deaths occurred among ESRD (dialysis and transplant) patients (Ziemba et al. 2021). The estimated number of excess deaths per 1,000 patients and total excess deaths were two to three times higher among dialysis patients than among kidney transplant patients. According to the United States Renal Data System, compared with the same period in 2017 through 2019, all-cause mortality among dialysis patients across all insurance types in 2020 was 37 percent higher during epidemiologic weeks 14 through 17 (April 2020) and 16 percent higher during weeks 18 through 27 (May 2020 through the beginning of July 2020). Among patients with a functioning transplant, corresponding estimates of excess mortality for 2020 versus 2017 through 2019 were 61 percent and 26 percent, respectively (United States Renal Data System 2021c).
- The growing trend toward home dialysis under the ESRD PPS continued in 2020 and is likely linked to the pandemic as well as to other factors, including the Center for Medicare & Medicaid Innovation's new model that aims to encourage greater use of home dialysis. According to the LDOs, interest in home dialysis has increased among their patients. One LDO (Fresenius Medical Care) reported a rise in home dialysis trainings in 2020 compared with 2019 (Charnow 2020).
- Between 2019 and 2020, the number of kidney transplants declined by 2 percent. The number of live donor procedures declined by 24 percent, while the number of deceased donor procedures grew by 6 percent. Fewer kidney transplants in 2020 is linked to elective case restrictions imposed by some centers as well as suspension of living donor kidney programs out of concern for donor and recipient safety.
- CMS suspended the collection of certain quality data.

(continued next page)

The coronavirus public health emergency and the Commission's assessment of payment adequacy for outpatient dialysis services (cont.)

- A Medicare payment policy change increased payments to all health care providers by suspending the 2 percent sequestration beginning May 2020 through December 2021. In 2022, the sequestration is suspended until March 31 and is set at 1 percent from April 1 until June 30.
- Although both LDOs have incurred increased costs (e.g., personal protective equipment (PPE), testing, and establishing isolation centers for infected patients) due to the PHE, in general the PHE has had a lesser impact on their operations during the third quarter of 2020 compared with the second quarter. In addition, higher pandemic-related expenses were partly offset by savings associated with the pandemic in the form of reduced travel and other items. During the PHE, LDOs' commercial-payer mix of patients (which is linked to each company's financial performance) has remained relatively steady or improved.

Some dialysis providers benefited from federal grants and loans and other temporary policy changes (such as granting exceptions for the collection of quality data used in the Quality Incentive Program) that eased the PHE's impact of lower volume (and its associated revenue) and higher costs for staffing, PPE, and testing. (See Chapter 2 for a description of the COVID-19 relief laws that provided relief funds to health care providers.) For example, Fresenius Medical Care accepted funds under the Coronavirus Aid, Relief, and Economic Security, or CARES, Act of 2020, while DaVita returned such funds. As applicable, more information about the impact of the pandemic on dialysis providers can be found throughout this chapter.

While the PHE has not changed the nature of dialysis care (multiple treatments per week), providers have coordinated with each other to ensure that capacity is sufficient to treat all patients. For example, multiple dialysis providers—including DaVita, Fresenius Medical Care, U.S. Renal Care, American Renal Associates, Satellite Healthcare, and others—formed the Dialysis Community Response Network to coordinate care for patients when certain units are overwhelmed with either staff-related or patient-related COVID-19 illness (Kosman and Williamson 2020).

In this chapter, we recommend payment rate updates for 2023. Because of standard data lags, the most recent complete data we have are from 2020 for most payment adequacy indicators. The coronavirus PHE has created additional data lags, most notably for cost reports, due to extensions of reporting deadlines. We use available data as well as changes in payment policy to project margins for 2022 and make payment recommendations for 2023. To the extent that the effects of the coronavirus PHE are temporary changes or vary significantly across individual dialysis facilities, they are best addressed through targeted temporary funding policies rather than a permanent change to all providers' payment rates in 2023 and future years. For each payment adequacy indicator in this chapter, we discuss whether the effects of the PHE on those indicators will most likely be temporary or permanent. Only permanent effects of the pandemic will be factored into recommended permanent changes in Medicare base payment rates. (For an overview of how our payment adequacy framework takes account of the PHE, see Chapter 2.) ■

to 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 2020. Among facilities that furnished home dialysis, the share of total treatments that were furnished in the home rose from an average of 24 percent to 29 percent. (At the 75th percentile of facilities, the share increased from 28 percent to 32 percent, consistent with a rise in the

share of FFS dialysis beneficiaries receiving home dialysis.)

Providers of outpatient dialysis services In 2020, there were roughly 7,800 dialysis facilities in the United States that furnished about 44.3 million Medicare-paid treatments to FFS dialysis beneficiaries. In 2020, FFS Medicare accounted for 57 percent of all treatments furnished.²³ According to CMS facility survey data, since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments. In 2020, freestanding facilities furnished 96 percent of FFS treatments, and for-profit facilities furnished 89 percent (Table 6-2, p. 205). In 2020, 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 2020, 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 as well as 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. In 2009, the Commission recommended that the Congress require all hospitals and other entities that bill Medicare to annually report the ownership share of each physician who directly or indirectly owns an interest in the entity (excluding owners of publicly traded stock) and that the Secretary should post this information on a searchable public website (Medicare Payment Advisory Commission 2009).

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 2019 with beneficiaries treated at facilities that provided dialysis in 2019 and 2020.

Between 2019 and 2020, the number of dialysis treatment stations—a measure of providers' capacity—rose by 1 percent (Table 6-2, p. 205). 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, facilities that closed in 2019 (about 90 facilities) were more likely to be hospital based and small (as measured by the number of dialysis treatment stations), which is consistent with long-term trends in the supply of dialysis providers.

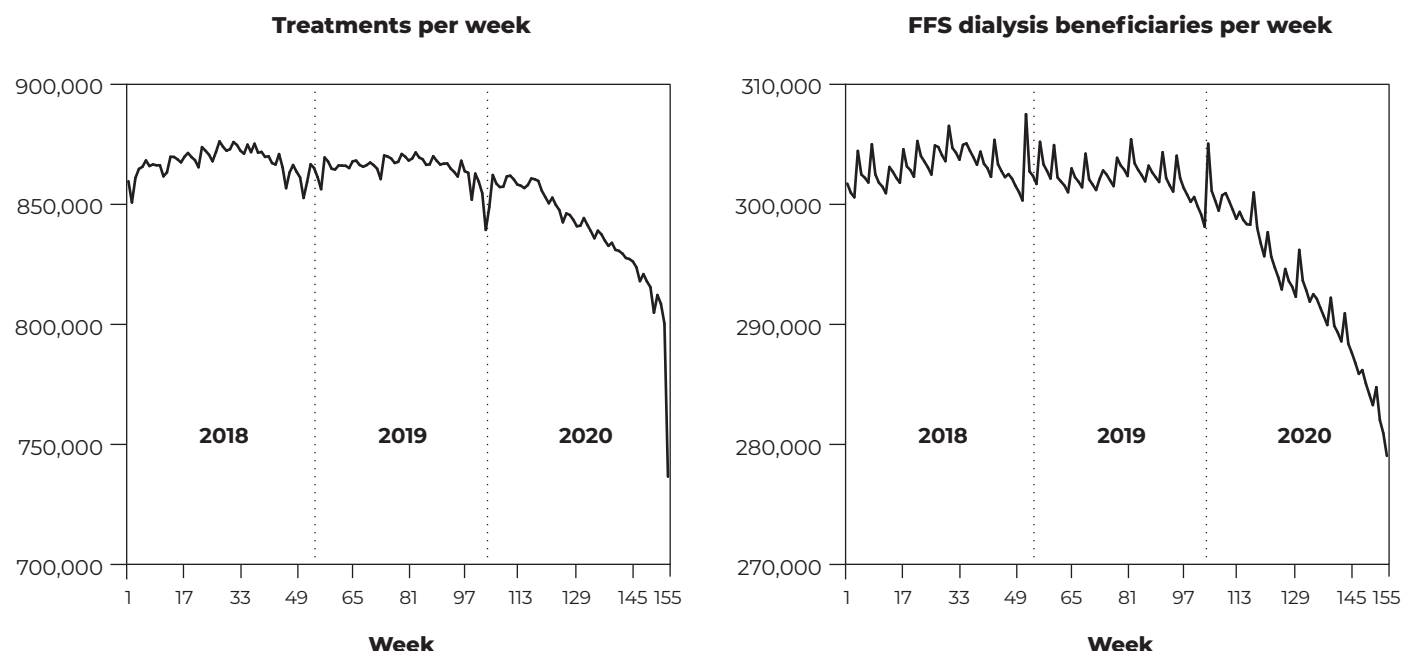
According to our analysis, few dialysis FFS beneficiaries (roughly 2,400 individuals) were affected by facility closures in 2019. Our analysis found that beneficiary groups who were disproportionately affected included White beneficiaries and beneficiaries residing in rural areas. However, less than 1 percent of FFS beneficiaries residing in rural areas were affected by facility closures. Our analysis of claims data suggests that beneficiaries affected by these closures obtained care elsewhere.

Volume of services

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

Trends in number of dialysis treatments provided

Between 2018 and 2020, there was a decline in both the number of FFS dialysis beneficiaries (roughly 395,000 beneficiaries in 2018 and 2019 compared with 384,000 beneficiaries in 2020) and the total Medicare-covered dialysis treatments (45.5 million treatments in 2018, 45.4 million treatments in 2019, and 44.3 million treatments in 2020). Figure 6-1 shows the decline in the number of beneficiaries and treatments per week in 2019 and 2020. This decline is largely attributable to the coronavirus pandemic, which resulted in slowing

**FIGURE
6-1****In 2020, weekly number of FFS dialysis beneficiaries and treatments declined**

Note: 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 variation in the weekly number of beneficiaries and treatments may also be linked to seasonal factors.

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

the initiation of dialysis by new patients and in excess mortality. The variation in the weekly number of beneficiaries and treatments may also be linked to seasonal factors. The number of dialysis treatments per beneficiary remained steady at 115 (data not shown).²⁴ Over the most recent five-year period for which we have data (2015 to 2020), the number of FFS dialysis beneficiaries and total dialysis treatments declined slightly (by 0.2 percent per year and 0.1 percent per year). The five-year trend in the relatively low annual growth in FFS dialysis beneficiaries is likely attributable to the increase in dialysis beneficiaries enrolled in MA plans during this period.

Use of most ESRD-related drugs in the PPS bundle 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 dialysis drugs included in the payment bundle. When CMS broadened the payment bundle in 2011 to include ESRD-related drugs that previously were billed separately, the agency set the PPS payment rate based on a per treatment basis using claims data from 2007. In 2014, to account for the decline in dialysis 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 2020 (the most current year for which complete data are available) in the use per treatment for the leading dialysis drugs and aggregated them into four therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics.²⁵

**TABLE
6-3****Under the ESRD PPS, use per treatment of dialysis drugs has declined, shifting to less costly clinically similar products**

Dialysis drug	Mean units per treatment*			Aggregate percent change	
	2010	2019	2020	2010-2020	2019-2020
ESAs					
Epoetin alfa (reference)	5,214	1,206	1,105	-79%	-8%
Darbepoetin alfa	1.26	0.9	0.8	-33	-6
Epoetin beta	N/A	4.5	4.3	N/A	-6
Epoetin alfa (biosimilar)	N/A	33.4	77.1	N/A	128
Iron agents					
Sodium ferric gluconate	0.15	0.1	0.1	-61	-27
Iron sucrose	16.0	13.2	12.5	-22	-5
Ferumoxytol	0.8	0.004	0.004	-100	-11
Ferric carboxymaltose	N/A	0.0001	0.0002	N/A	16
Ferric pyrophosphate citrate (solution)	N/A	0.03	0.03	N/A	-11
Ferric pyrophosphate citrate (powder)	N/A	N/A	0.4	N/A	N/A
Vitamin D agents					
Paricalcitol	2.3	0.3	0.2	-90	-6
Doxercalciferol	0.9	1.3	1.3	49	-1
Calcitriol	0.13	0.01	0.02	-87	71
Antibiotics					
Daptomycin	0.22	0.1	0.05	-79	-42
Vancomycin	0.02	0.01	0.01	-70	-30
Other drugs					
Levocarnitine	0.010	0.001	0.001	-94	-10
Alteplase	0.020	0.002	0.002	-90	1

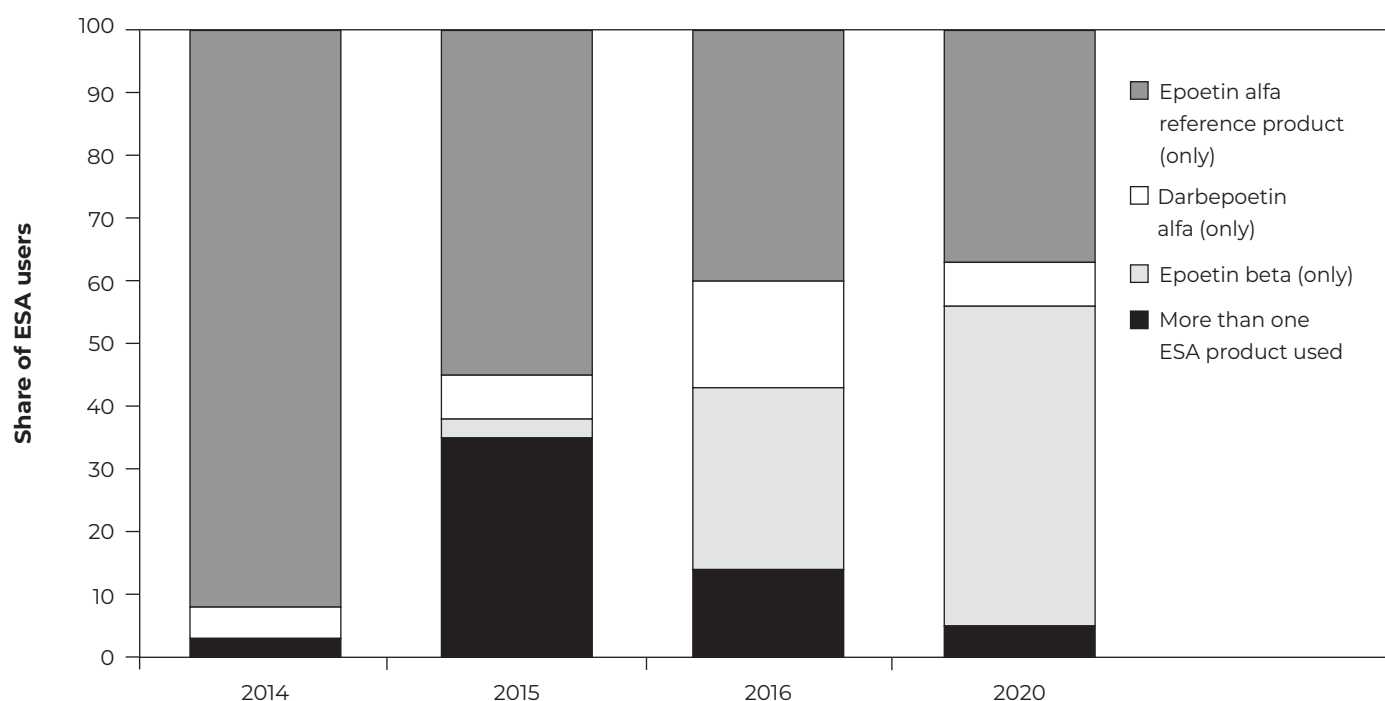
Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent), N/A (not applicable because drug not available in the U.S.). Individual units per treatment are rounded; the aggregate percent change is calculated using unrounded units per treatment.

*Each drug is reported using its own drug units.

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

As shown in Table 6-3, use of all ESRD-related drugs available between 2019 and 2020 declined except for biosimilar epoetin alfa (which was launched in late 2018), ferric carboxymaltose, calcitriol, and alteplase. The shift over time in the use of products within the ESA and vitamin D therapeutic classes is linked to price competition among the products within each class. For example, Figure 6-2 shows the shift in ESA use from epoetin alfa and darbepoetin alfa to the less

costly epoetin beta. In at least one situation, switching was an explicit goal: One of the LDOs announced its intent to have more than 70 percent of the company's ESA patients (110,000 patients) switched to epoetin beta (from epoetin alfa) by the end of the first quarter of 2016 (Reuters 2016).²⁶ According to several sources, the LDO reduced its total ESA costs by switching beneficiaries to epoetin beta (Reuters 2016, Seeking Alpha 2016). A midsize chain announced that between

**FIGURE
6-2****Under the ESRD PPS, use of ESAs shifted due to price competition**

Note: ESRD (end-stage renal disease), PPS (prospective payment system), ESA (erythropoiesis-stimulating agent). Epoetin beta became available in 2015. The share of beneficiaries using only epoetin alfa biosimilar is less than 5 percent of all ESA users (and not included in the above figure).

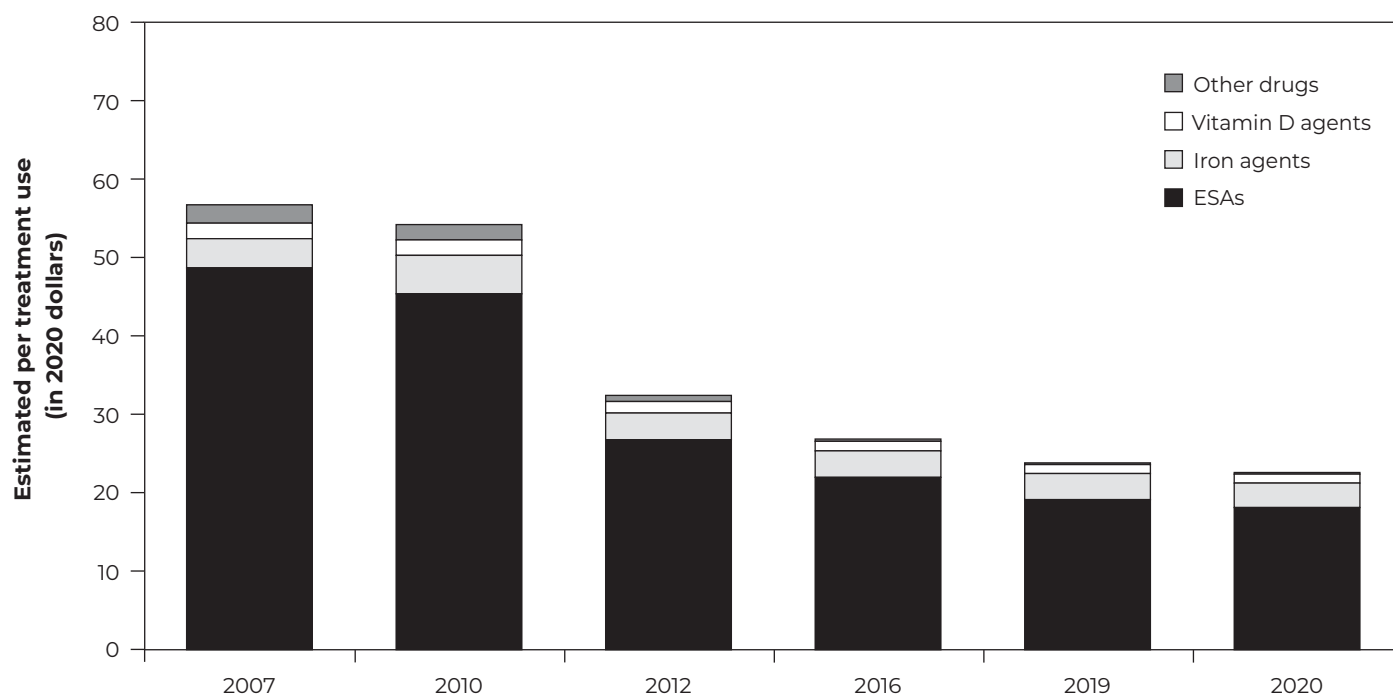
Source: MedPAC analysis of claims submitted by dialysis facilities to CMS.

85 percent and 90 percent of its facilities switched to epoetin beta by the end of 2018 (Seeking Alpha 2018).

As shown in Figure 6-3 (p. 212), most of the decline in the per treatment use of ESRD drugs occurred in the early years of the PPS.²⁷ (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.) For example, between 2010 and 2012, use per treatment across all therapeutic classes declined by 23 percent per year. Most of this decline was due to declining ESA use, which also fell by 23 percent per year during the same period. For ESAs, some of this decline 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 2019 and 2020, holding price constant, the

use of all dialysis drugs in the four classes declined by 5 percent. 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).

Use of ESRD drugs paid under the TDAPA remained relatively steady in 2020 Our analysis of dialysis drug use also examines beneficiaries' use of the calcimimetics paid for under the TDAPA policy—Sensipar (cinacalcet), the oral product, and Parsabiv (etelcalcetide), the injectable product. Before 2018, Medicare covered the oral calcimimetic under Part D. After the FDA approved the injectable calcimimetic Parsabiv in 2017, Medicare began to pay for both

**FIGURE
6-3****Use of ESRD-related drugs in the payment bundle
has declined under the outpatient ESRD PPS**

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). The ESRD drugs in this analysis are included under the outpatient ESRD PPS bundle and paid under the base payment rate. That is, included drugs are those for which Medicare paid dialysis facilities separately before the ESRD PPS or are in 1 of the 11 functional categories of drugs included in the ESRD PPS bundle. Drugs included are epoetin alfa, epoetin beta, and darbepoetin (ESAs); iron sucrose, sodium ferric gluconate, ferumoxytol, and ferric carboxymaltose (iron agents); calcitriol, doxercalciferol, and paricalcitol (vitamin D agents); daptomycin, vancomycin, alteplase, and levocarnitine (all other drugs).

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

products under the ESRD PPS (Medicare Part B) in 2018. In 2021, both products are included and paid for under the PPS bundle.

Between 2019 and 2020, TDAPA spending for both calcimimetics declined by 44 percent, from nearly \$1.3 billion to \$712 million. This spending decline is linked to the following:

- In 2020, CMS lowered the TDAPA payment to 100 percent of each drug's ASP.²⁸ In 2018 and 2019, CMS paid facilities 106 percent of each drug's ASP.
- Generic versions of the oral product (Sensipar) were launched. Typically, when generic versions of a drug enter the market, their sales prices are substantially lower than those of the drug's brand equivalent. Brand and generic versions of a multiple-source drug are assigned to the same billing code and paid the same rate, equal to the volume-weighted average ASP. Between 2019 and 2020, Sensipar's (and its generics') payment rate (ASP + 0 percent) decreased by 70 percent, from an average \$0.75 per unit to an average \$0.23 per unit.

Use patterns of the calcimimetics in 2020 were generally similar to those seen during the first two years of the TDAPA (2018 and 2019). In each year, about one-third of dialysis beneficiaries were prescribed a calcimimetic. The share of beneficiaries receiving Parsabiv increased from 7 percent in 2018 to 10 percent in 2019 and 2020, while the share of beneficiaries receiving Sensipar (and its generics) ranged from 28 percent in 2018 to 24 percent in 2020.

Dialysis marginal profitability suggests incentive to serve Medicare beneficiaries 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 marginal revenue it will receive (i.e., the Medicare payment) with its marginal costs—that is, the costs that vary with volume. If Medicare payments are larger than the marginal costs of treating an additional beneficiary, a provider has a financial incentive to increase its volume of Medicare beneficiaries 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.²⁹

For dialysis facilities in 2020, Medicare payments exceeded dialysis facilities' marginal costs by 20 percent, a positive indicator of patient access in that facilities with available capacity have an incentive to treat Medicare beneficiaries.

Quality of care is difficult to assess

Quality of care is challenging to interpret due to effects of the PHE on many of our measures. While we report 2020 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 2020. Many factors related to the coronavirus pandemic, including hospital capacity constraints and patient avoidance of health care settings, affected rates of hospitalizations. Mortality rates increased during 2020 due to COVID-19 and possibly due to patient avoidance of health care for other illnesses, such as stroke. Also, current measures use risk-adjustment models that examine performance from previous years to predict beneficiary risk, so they may not adequately represent the acuity and mix of patients receiving care in 2020.

Our analysis focuses on changes in quality indicators—including mortality and morbidity, process measures that assess dialysis adequacy and anemia management, and treatment utilization (including home dialysis and kidney transplantation rates). The findings, except where indicated, are based on the Commission's analysis of Medicare FFS enrollment and claims data.

In assessing quality, we also examine the multiple factors that affect access to kidney transplantation. This procedure is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical outcomes, quality of life, and Medicare spending, but demand far outstrips supply.

Quality under the ESRD PPS

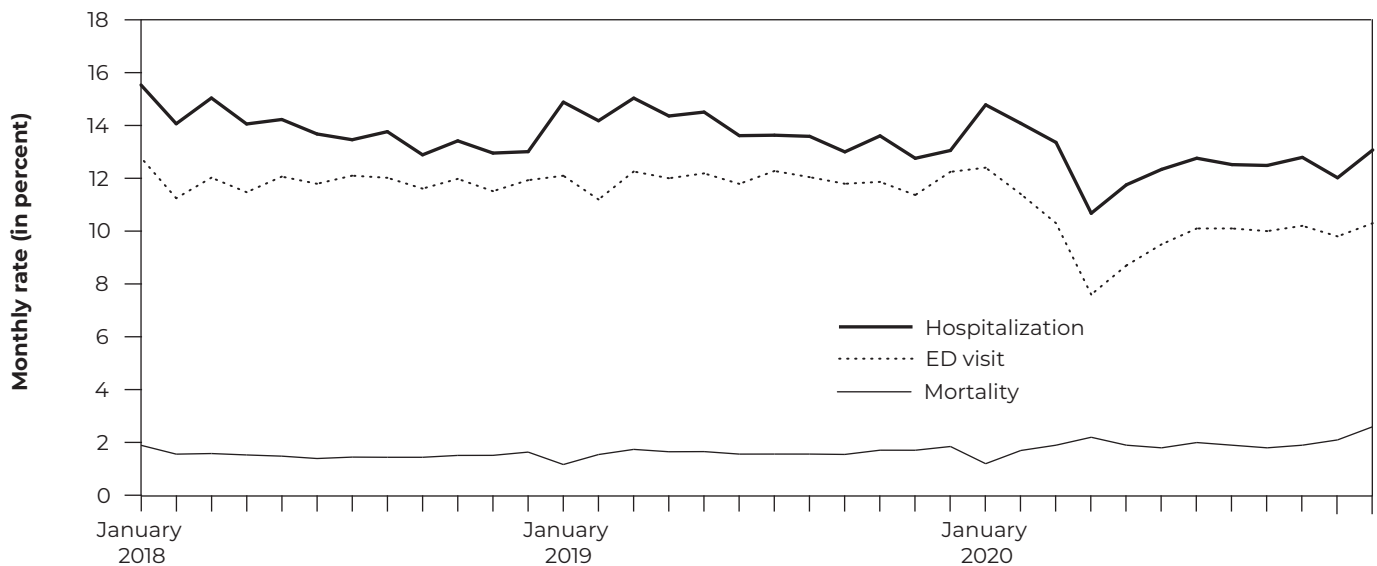
Our analysis of claims and enrollment data for FFS dialysis beneficiaries suggests that all-cause hospitalization and emergency department (ED) use declined in 2020 compared with prior years, while mortality increased (Figure 6-4, p. 214).

- In 2018 and 2019, the share of FFS dialysis beneficiaries admitted to a short-stay hospital (beneficiaries with at least one admission in a given month) was 14 percent per month. In 2020, the hospitalization rate averaged 13 percent per month. Between 2018 and 2020, 30-day readmission rates on an annual basis remained relatively steady at 22 percent of admissions (data not shown).
- In 2018 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, the ED use averaged 10 percent per month.
- Between 2018 and 2019, mortality remained relatively unchanged, at 1.6 percent per month. In 2020, the rate of mortality per month increased to 1.9 percent.

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 2015 and 2019, from 97 percent to 98 percent of hemodialysis beneficiaries and from 91 percent to 93 percent of PD beneficiaries received adequate dialysis.

**FIGURE
6-4**

Morbidity and mortality among FFS dialysis beneficiaries, 2018–2020



Note: FFS (fee-for-service), ED (emergency department). All-cause hospitalization and outpatient ED rates are measured by at least one encounter for the service in a given month.

Source: MedPAC analysis of claims submitted by dialysis facilities to CMS and CMS's enrollment file.

In 2020, 98 percent of hemodialysis beneficiaries and 93 percent of PD beneficiaries received adequate dialysis.

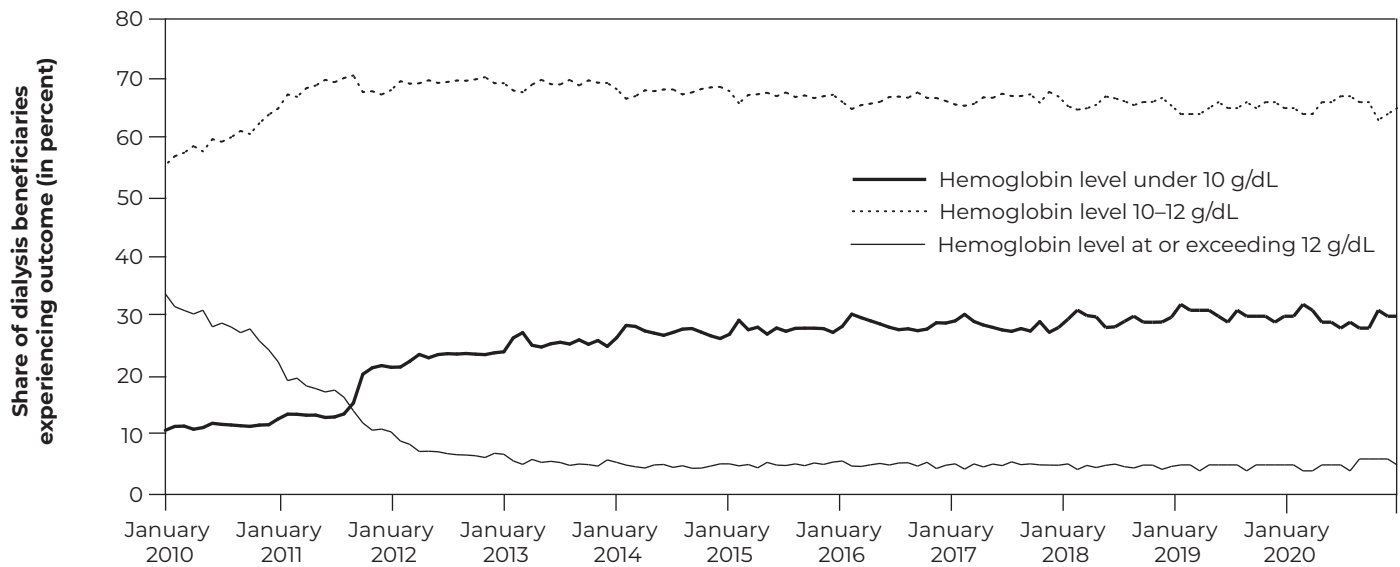
We assess anemia management by examining trends over time in (1) beneficiaries' hemoglobin level, a blood test that measures the level of hemoglobin, the protein that carries oxygen in red blood, and (2) frequency of red blood cell transfusions.³⁰ Lower hemoglobin levels (which may suggest underuse of ESAs and iron agents) may increase the frequency of red blood cell transfusions, while higher hemoglobin levels (greater than 11 g/dL) among patients maintained on higher doses of ESAs may increase their risk of death and cardiovascular events (congestive heart failure, myocardial infarction, and stroke).

Median hemoglobin levels fell during the initial years of the ESRD PPS, then stabilized; between 2015 and 2019, median levels ranged between 10.4 g/dL and 10.5 g/dL. In 2020, the median level was 10.5 g/dL. Figure 6-5

shows that the proportion of dialysis beneficiaries with higher hemoglobin levels declined (exceeding 12 g/dL) while the proportion with lower hemoglobin levels increased (which is generally associated with lower ESA use). According to CMS, during the initial years of the ESRD PPS (2010 and 2012), blood transfusion rates increased (from 2.7 percent per month to 3.4 percent per month). Between 2013 and 2020, however, the proportion of beneficiaries receiving a blood transfusion declined (from 3.3 percent per month to 2.4 percent per month), according to data from the Commission and CMS (Centers for Medicare & Medicaid Services 2019). These findings—the decline in hemoglobin levels and increase in transfusion rates during the early years of the ESRD PPS—are consistent with the incentives under the prior and current ESRD payment methods. The pre-2011 payment method (which paid providers according to the number of units of each drug administered) gave some providers the incentive to overutilize dialysis drugs, while the current payment method

**FIGURE
6-5**

**Changes in hemoglobin levels
under the ESRD PPS, 2010–2020**



Note: ESRD (end-stage renal disease), PPS (prospective payment system), g/dL (grams per deciliter). Data are compiled on a monthly basis by CMS.

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

gives providers the incentive to be more judicious in providing drugs included in the payment bundle.

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 2015 and 2019, the share of beneficiaries dialyzing at home increased from 10.6 percent per month to 12.3 percent per month. In 2020, the share of beneficiaries on home dialysis increased to an average of 13.3 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 35 percent of Medicare beneficiaries with ESRD are Black, but only 26 percent of beneficiaries who dialyze at home are Black. Between 2015 and 2020, the proportion of beneficiaries undergoing home dialysis training was relatively small but increased slightly, ranging from a monthly average of 0.7 percent to 0.8 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 PHE, however, both LDOs and midsize providers reported that their patients showed increased awareness of and interest in home dialysis.³¹

Some clinical and nonclinical factors affecting home dialysis use are amenable to intervention. For example, between 2008 and 2018, under an integrated

**TABLE
6-4****In 2020, decline in the number of kidney transplants
was due to the coronavirus pandemic**

	2015	2019	2020
Total transplants	17,878	23,401	22,817
Share of transplants from live donors	31%	29%	23%
Share receiving a transplant			
White	50	46	45
Black	25	28	27
Hispanic	16	17	18
Asian	6	6	7
Other	2	2	2

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

Source: Organ Procurement and Transplantation Network.

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 2018, average Medicare spending for patients who had a functioning kidney transplant was less than half of the spending for dialysis patients (\$38,800 vs. \$93,300) (United States Renal Data System 2021a). 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 2015 and 2019, according to the Organ Procurement and Transplantation Network, the number of kidney transplants increased by 7 percent per year, to 23,401 (Table 6-4). In 2020, the 2 percent decline (to 22,817 transplants) in the number of kidney transplants was mostly attributable to the decline in live donors due to the coronavirus pandemic. In spring 2020, 81 percent of transplant centers in regions of the country with a high cumulative COVID-19 prevalence (greater than 500 cases per 100,000 people) chose to internally suspend their living donor kidney programs out of concerns for donor and recipient safety, and there were elective case restrictions (UNOS 2021). In addition, some transplant centers slowed transplants of kidneys (as well as other organs) to protect bed capacity and staff safety (Greene 2020). As a result, between 2019 and 2020, the number of transplants from live donors declined by 24 percent to 5,234 transplants, while the number from deceased donors

rose by 6 percent to 17,583 transplants; in contrast, between 2015 and 2019, live and deceased donors rose by 5 percent and 8 percent, respectively, per year on average (data not shown).

The distribution of transplants by race and ethnicity in 2020 is similar to the distribution between 2015 and 2019 (Table 6-4). Between 2015 and 2019, Blacks were less likely than Whites to receive kidney transplants despite their three-times greater likelihood of developing ESRD. In 2020, the number of Blacks and Asians receiving a transplant each declined by 1 percent, while the number of Whites and Hispanics receiving a transplant each declined by 4 percent (data not shown). According to Ephraim and colleagues, the lower rates of kidney transplantation for Blacks have been associated with multiple factors, including immunological incompatibility with deceased donor kidneys, lower rates of referral for transplantation, lower rates of cadaver kidney donation, and lack of knowledge and suboptimal discussions about kidney transplantation among recipients, their families, and health care providers (Ephraim et al. 2012).

Education efforts directed at patients can be effective in encouraging them to make an informed decision about their treatment, including home dialysis, in-center dialysis, kidney transplantation, and conservative care. For example, a recent review of educational interventions found a strong association between patient-targeted dialysis modality education and choosing and receiving PD (Devoe et al. 2016). An augmented nurse care management program that targeted persons with late-stage CKD resulted in a statistically significant reduction in the number of hospitalizations during the intervention period and, for those who required renal replacement therapy, higher use of PD or a preemptive kidney transplant (Fishbane et al. 2017).

In 2010, to help inform beneficiaries diagnosed with Stage 4 CKD (the disease stage before ESRD) about their treatment options and managing the disease and related comorbidities, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) established Medicare payment for up to six sessions of kidney disease education (KDE) per beneficiary. Since its implementation, relatively few beneficiaries have been provided KDE services. Between 2015 and 2019,

spending declined by 5 percent per year to nearly \$420,000.³² In 2020, KDE spending declined by an additional 21 percent to \$330,000.

According to the Government Accountability Office, payment restrictions on the type of providers who can furnish KDE services and the beneficiaries who are eligible might constrain the service's use (Government Accountability Office 2015). MIPPA specified the categories of providers who can furnish KDE services—physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certain providers of services in rural areas.³³ MIPPA also specified that beneficiaries with Stage 4 CKD are eligible for the benefit. Some stakeholders contend that other categories of beneficiaries, including those with Stage 5 CKD (i.e., ESRD) who have not started dialysis, as well as individuals who have already initiated hemodialysis, might also benefit from Medicare KDE coverage.

Providers' access to capital: Growth trends indicate 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 requiring dialysis. The two LDOs as well as other renal companies appear to have had adequate access to capital. For example:

- In 2021, Fresenius Medical Care invested an additional \$25 million in Humacyte Inc. after an initial investment of \$150 million in 2018. Humacyte Inc. is developing bioengineered human tissue, including a product for use as vascular access for hemodialysis patients. In addition, in 2021, Fresenius opened a new technology center for developing dialysis machines in Germany.
- In 2021, DaVita sought to acquire a hospital-based dialysis organization in Utah. The company has noted investments in technologies (e.g., artificial intelligence to identify home dialysis patients at risk for hospitalization) used to expand its integrated care and value-based care initiatives in 2021.

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 addition to private sector investment in renal care, in 2018, a public-private partnership between the Department of Health and Human Services and the American Society of Nephrology was initiated to accelerate innovation in the prevention, diagnosis, and treatment of kidney disease. This initiative—referred to as the Kidney Innovation Accelerator (KidneyX)—sponsors cash-prize competitions. For example, there is currently a competition to accelerate artificial kidney development toward human clinical trials.

In public financial filings, the two LDOs reported generally positive financial performance related to their dialysis business for 2020, 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 2020 all-payer margin was roughly 16 percent. Including PHE provider-relief revenues increases the 2020 all-payer margin to roughly 17 percent. 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

Each year, we examine the relationship between Medicare's payments and providers' costs as part of our assessment of payment adequacy. To make this assessment, we reviewed Medicare expenditures for outpatient dialysis services in 2020 and examined trends in spending under the PPS. We also reviewed evidence regarding providers' costs under the PPS.

Medicare payments for outpatient dialysis services

In 2020, Medicare spending for outpatient dialysis services was \$12.3 billion, a decrease of 4 percent compared with 2019; per capita spending declined by 1 percent to roughly \$32,200. Between 2019 and 2020, dialysis spending for services in the bundle (which accounts for 90 percent of total spending) grew by 0.1 percent, while TDAPA spending (which accounts for 6 percent of total spending) declined by 44 percent. As mentioned earlier, in 2020, CMS changed the TDAPA payment from ASP + 6 percent to ASP with no percentage add-on. Other factors affecting spending growth include (1) a statutory update (of 1.7 percent) to the base dialysis payment rate in 2020, (2) a 3 percent decline in the total number of dialysis treatments furnished between 2019 and 2020, and (3) the number of dialysis treatments per beneficiary holding steady in both years (averaging 115 treatments per beneficiary).

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 2020, Medicare spending for outpatient dialysis services for beneficiaries with AKI was \$77 million, an increase from nearly \$71 million in 2019. Medicare pays facilities the ESRD PPS base rate adjusted by the PPS wage index for the treatment of beneficiaries with AKI.³⁴ Researchers have found that AKI is a serious complication of COVID-19. 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.

Between 2018 and 2019, Part D spending for ESRD oral-only phosphate binders declined

As of 2019, phosphate binders are the only ESRD oral-only drug class that is paid for under the Part D program, and roughly 70 percent of dialysis beneficiaries with Part D coverage were prescribed such drugs in 2019.³⁵ Between 2018 and 2019 (the most recent year data are available), spending for phosphate binders furnished to dialysis FFS beneficiaries declined by 19 percent to \$0.9 billion. This decline is linked to the FDA's approval of generic versions of several types of phosphate binders (including lanthanum, sevelamer carbonate, and sevelamer hydrochloride) between 2017 and 2019. In 2019, Part D spending for phosphate binders accounted for 36 percent of Part D spending for dialysis beneficiaries. Medicare spending for dialysis 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 2018 and 2019:

- 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 its 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 efficient providers would incur in furnishing high-quality care. For this analysis, we used 2019 and 2020 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 PPS Between 2019 and 2020, total cost per treatment rose by 4 percent, from \$255 per treatment to roughly \$266 per treatment. The increase was driven by higher cost per treatment for:

- supplies and labor, which rose by 8 percent and 6 percent. Together, these cost categories accounted for 45 percent of providers' cost per treatment.
- non-ESA drugs (e.g., vitamin D agents, iron agents, calcimimetics, and so-called composite rate drugs (i.e., drugs that Medicare paid for under the prior PPS)), which increased by 8 percent and together accounted for 5 percent of cost per treatment. Cost growth for non-ESA drugs may have been affected by facilities associated with one dialysis organization misreporting its costs for this category in 2019.
- administrative and general expenses, which rose by 7 percent and accounted for 25 percent of cost per treatment.
- capital costs, which rose by 3 percent and accounted for 18 percent of cost per treatment.

By contrast, between 2019 and 2020, ESA cost per treatment declined (by 11 percent), while lab cost per treatment showed little change; together, these

cost categories accounted for 7 percent of cost per treatment.

In 2019, facilities associated with one dialysis organization reported a large amount of non-ESRD-related drug costs that was anomalous compared with prior years. In 2020, our analysis finds that these facilities (1) reported an amount of non-ESRD-related drug costs that was consistent with pre-2019 levels (i.e., was not anomalous) and (2) reported a substantial increase in the cost per treatment for non-ESA drugs compared with 2019, which is not consistent with the decline in cost per treatment for this category on average across all other dialysis organizations. Consistent with our longstanding approach, non-ESRD-related drug costs are not included in the Commission's analysis of ESRD PPS costs incurred by freestanding dialysis facilities or in our calculation of the ESRD PPS margin.

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 2019 and 2020, per treatment costs fell by 5 percent for facilities in the 25th percentile of cost growth, compared with a rise of 5 percent for facilities in the 75th percentile.³⁶

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, between 2019 and 2020, the cost per treatment among these organizations for capital and labor each varied by nearly \$40 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. CMS's Office of the Actuary (OACT) selected a sample of 1,479 freestanding ESRD facilities from 5 large dialysis organizations (as defined by OACT) for the cost audit. A contractor performed cost audits of these ESRD facilities in September of 2015. All audits were completed by September of 2018.

According to the agency, of the 1,395 ESRD freestanding facilities analyzed, \$147.5 million of unallowable costs were removed from total costs, including the removal of \$136.5 million of unallowable costs initially reported in the administrative and general cost center. Unallowable items included advertising, legal fees, interest expense and financing fees, corporate travel/lodging/relocation, various consulting fees, business development expenses, insurance settlement payments, and insurance expenses. CMS concluded that, based on this audit, cost report data were corrected.

In our comment letter to CMS, we said that the agency should provide the total reported costs and total unallowable costs, which would enable us to compare the results of this audit with prior audits that found that providers' allowable costs were about 90 percent to 96 percent of reported costs (Medicare Payment Advisory Commission 2021). We also said that CMS should publish the same statistics by cost report category (i.e., for capital, labor, supply, laboratory, general and administrative, composite rate drugs, ESAs, and other drug costs) as well as background information about the number, types, and size of facilities included in the audit.

Because CMS did not publish total reported costs for the 1,395 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 \$147.5 million in unallowable costs represents about 4 percent of reported costs in 2018.³⁷ Our estimate assumes 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, then 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 areas and included all treatments regardless of payer.

Our analysis showed, in each year from 2011 through 2020, a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equaled -0.5) (Figure 6-6). That is, the greater the facility's service volume, the lower its costs per treatment. In each year, facilities that qualified for increased Medicare payment due to low volume had substantially higher cost per treatment for capital as well as administrative and general services compared with all other facilities.

The trend in the aggregate Medicare margin for freestanding dialysis facilities

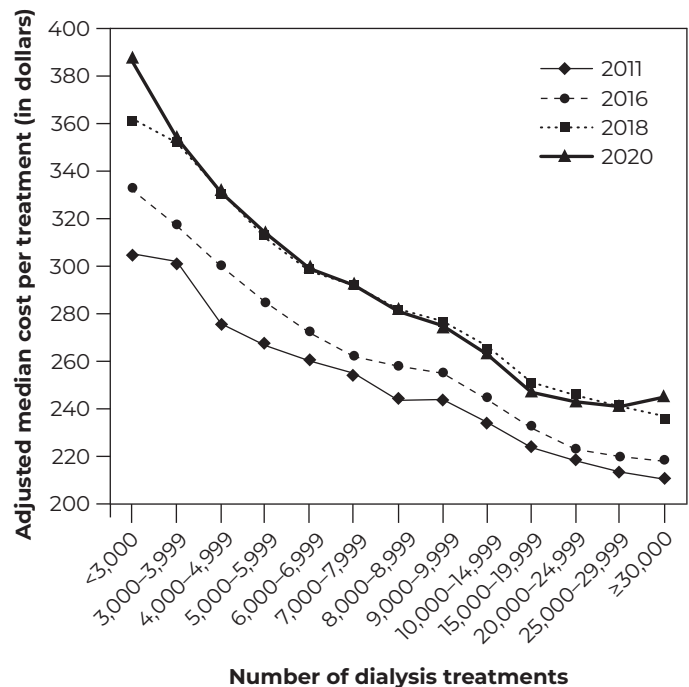
The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with facilities' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2020.

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 6-7, p. 222). During the initial years of the ESRD PPS, the aggregate Medicare margin increased, particularly because of declining use of ESRD drugs between 2010 and 2012 (Table 6-3, p. 210). 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 dialysis 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 2018.³⁸

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 6-7, p. 222).³⁹ 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

FIGURE 6-6

Higher-volume dialysis facilities have lower cost per treatment, 2011–2020

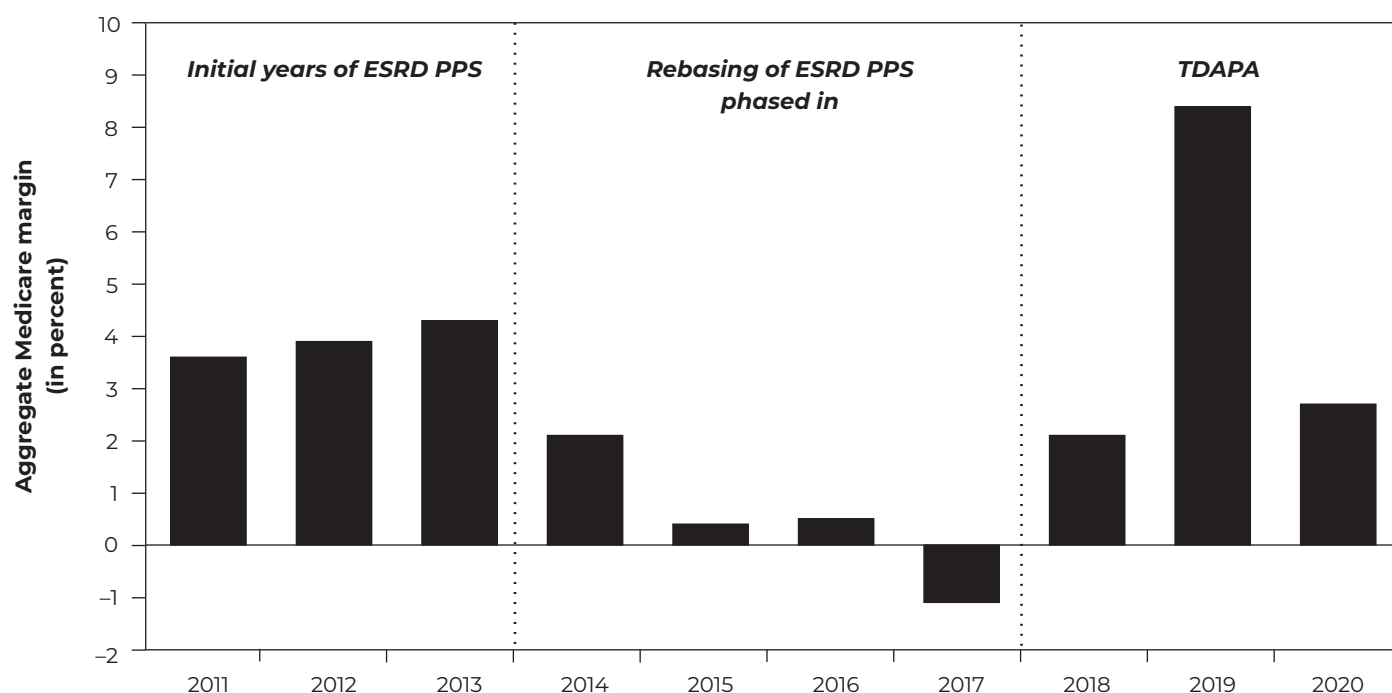


Note: Cost per treatment is adjusted to remove differences in the cost of labor. "Dialysis facilities" includes those paid by all insurance sources.

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

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 used by Medicare 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 6-7, p. 222). This decline is linked to increasing cost per treatment for all cost

**FIGURE
6-7****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 accounted for in the data presented in this figure.

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

categories with the exception of ESAs and labs and to the TDAPA payment declining from ASP + 6 to ASP + 0. As discussed earlier, we include a portion of the congressional pandemic relief funds (based on FFS Medicare's share of 2019 all-payer operating revenue) in our aggregate Medicare margins 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).

The aggregate Medicare margin varies by treatment volume

Aggregate Medicare margins in 2020 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. -1.5 percent). Total treatment volume accounted for much of the difference in margins between urban and rural facilities. Urban dialysis facilities are larger on average than rural facilities in the number of treatment stations and total treatments provided. For example, in 2020, urban facilities averaged about 11,400 treatments, while rural facilities averaged about 7,800 treatments (data not shown). And, as shown in Figure 6-6 (p. 221), 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

**TABLE
6-5****In 2020, 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	2.7%	100%	100%
Urban	3.0	84	88
Rural	-1.5	16	12
Treatment volume (quintile)			
Lowest	-20.2	20	7
Second	-8.2	20	13
Third	0.3	20	18
Fourth	4.8	20	24
Highest	10.2	20	39

Note: Pandemic-related federal relief funds are not accounted for 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.

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 2022

We project the aggregate Medicare margin for 2022 to be 1.8 percent, less than the 2020 Medicare margin (2.7 percent). This projection considers providers' historical cost growth and the policy changes that went into effect between 2020 (the year of our most recent margin estimates) and 2022, which include the following:

- In 2021 and 2022, the statutory dialysis base payment rate (based on the ESRD market basket

offset by a productivity adjustment) increased by 1.6 percent and 1.9 percent, respectively.

- For 2022, a statutory change eliminates the 2 percent Medicare sequester through March 2022 and reduces the sequester to 1 percent beginning April 1, 2022, through June 30, 2022.
- For 2021, CMS estimates that payments will be reduced by 0.38 percent due to the ESRD Quality Incentive Program (QIP). No facility will receive a QIP-related payment reduction in 2022 due to the coronavirus pandemic's impact on the quality measures.
- For 2021, CMS estimates that payments will be reduced by 0.1 percent by including calcimimetics in the ESRD PPS bundle.
- For 2021 and 2022, the ESRD Treatment Choices (ETC) Model will increase providers' payments (net of reductions) by \$14 million and \$7 million, respectively.

Not included in the projection is the potential effect of:

- The new transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) that CMS will apply for a home dialysis machine beginning in January 2022. The technology will receive the TPNIES for two calendar years. CMS estimates that the TPNIES amount will equal an estimated \$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) beginning in April 2022 for a two-year period.

How should Medicare payments change in 2023?

The evidence suggests that outpatient dialysis payments are adequate. It appears that facilities have become more efficient under the PPS, as measured by declining use of most injectable dialysis drugs.

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 will 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 dialysis services is increased annually based on the projected increase in the market basket less a projected increase in productivity. Although the final update for 2023 will not be set until later in 2022, CMS's current projections of the market basket and productivity would result in the base payment rate increasing by 1.2 percent. In 2023, CMS estimates that the ETC Model will decrease payments to facilities by \$3 million (Centers for Medicare & Medicaid Services 2021).

RECOMMENDATION 6

For calendar year 2023, the Congress should update the 2022 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 PPS. Indicators of quality of care have generally remained stable; the use of home dialysis has increased, and hospital admissions and mortality have held steady, though emergency department use slightly increased. The aggregate Medicare margin was 2.7 percent in 2020 and is projected to be 1.8 percent in 2022. The 20 percent marginal profit is a positive indicator of beneficiary access.

Margins tend to be lower in low-volume and in rural dialysis facilities, in spite of the payment system's 23.9 percent low-volume adjustment and 0.8 percent rural adjustment. 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 those 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 adjusters 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 2023, 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 *biologics* refers to biological products.
- 2 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.
- 3 Throughout this chapter, we use the term “FFS Medicare” to mean the CMS term “Original Medicare.” Collectively, we distinguish the payment model represented by these terms from other models such as Medicare Advantage or advanced alternative payment models that may use FFS mechanisms but are designed to create different financial incentives.
- 4 In this chapter, the term *drugs* refers to both drugs and biologics.
- 5 According to the statute, dialysis oral-only drugs cannot be paid under the ESRD PPS bundle before January 1, 2025.
- 6 In 2020, the American Kidney Fund reported that it provided direct financial assistance to nearly 95,000 low-income dialysis and transplant patients (American Kidney Fund 2020).
- 7 For individuals entitled to Medicare based on ESRD benefit rules, Medicare coverage does not begin until the fourth month after the start of dialysis, unless the individual had a kidney transplant or began training for self-care, including dialyzing at home.
- 8 Under Level 1 of the CKCC Graduated Option, participants take one-sided risk (40 percent shared savings only; no shared loss rate); under Level 2, participants take two-sided risk (50 percent shared savings and 30 percent shared losses).
- 9 Under the Bipartisan Budget Act of 2018, beginning January 2019, clinicians who manage home-dialysis beneficiaries can furnish their visits through telehealth (rather than in person). Beneficiaries are required to receive a face-to-face visit in each of the first three months of home dialysis and once every three months thereafter.
- 10 CMS estimated that facilities’ payments would be reduced by \$35 million, while managing clinicians’ payments would be reduced by \$8 million. There would also be additional spending of \$15 million for kidney disease education and home training.
- 11 For pediatric dialysis beneficiaries (17 years of age and under), the base rate is adjusted for age and type of dialysis.
- 12 The Commission’s Payment Basics provides more information about Medicare’s method of paying for outpatient dialysis services (available at https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_dialysis_final_sec.pdf).
- 13 The Commission’s March 2014 report to the Congress provides more information about the rebasing of the dialysis base payment rate (available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar14_ch06.pdf).
- 14 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 https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-on-the-end-stage-renal-disease-prospective-payment-system-and-.pdf).
- 15 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 were paid under a TDAPA because the base dialysis payment rate has not yet accounted for their costs.
- 16 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.
- 17 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.
- 18 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.
 - 19 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. Note also that although one large dialysis organization manufactures ESRD drugs (included in the PPS bundle), the company currently does not manufacture a drug that is eligible for a TDAPA.
 - 20 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.
 - 21 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 MAC-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 (of \$9.32) that is intended to represent the portion of payment attributable to home dialysis machines from the base rate.
 - 22 Under Section 319 of the Public Health Services Act, the Secretary of Health and Human Services may determine that a disease or disorder presents a PHE or that a PHE, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. The Secretary first determined the existence of a coronavirus PHE, based on confirmed cases of COVID-19 in the United States, on January 31, 2020. At the time of publication, the coronavirus PHE had been renewed multiple times, most recently in January 2022.
 - 23 Based on the Commission's analysis of Medicare and total treatments reported by freestanding facilities on cost reports submitted to CMS.
 - 24 Treatments are non-annualized, meaning that the calculation does not account for each beneficiary's length of dialysis in a given year.
 - 25 These drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the new payment method.
 - 26 The FDA approved epoetin beta under the biologics license application process, not under the biosimilar process.
 - 27 To measure changes in the use of drugs in the payment bundle, we combine drugs within and across therapeutic classes by multiplying the number drug units reported on claims in a given year by each drug's 2021 ASP. By holding the price constant, we account for the different billing units assigned to a given drug.
 - 28 According to CMS, the agency decreased the TDAPA payment for calcimimetics from ASP + 6 percent to ASP because (1) facilities have had sufficient opportunity to address any administrative complexities and overhead costs associated with the provision of calcimimetics and (2) the agency needs to take into account the financial burden that increased payments place on beneficiaries and Medicare.
 - 29 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.
 - 30 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.
 - 31 See our March 2020 report to the Congress for more information on the factors that affect use of home dialysis and the factors associated with some patients'

- discontinuation of home dialysis (available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_medpac_ch6_sec.pdf).
- 32 This analysis used 100 percent of 2015 through 2020 carrier and outpatient claims submitted for KDE services.
- 33 MIPPA does not permit other providers (such as registered nurses, social workers, and dieticians) or dialysis facilities to bill for KDE services.
- 34 In addition, for beneficiaries with AKI, Medicare pays dialysis facilities separately for drugs, biologics, and laboratory services that are not renal dialysis services.
- 35 In 2018, about 90 percent of FFS dialysis beneficiaries were enrolled in Part D or had other sources of creditable drug coverage. About 10 percent of FFS dialysis beneficiaries in 2018 had either no Part D coverage or coverage less generous than Part D's standard benefit.
- 36 This analysis does not include facilities associated with the dialysis organization that reported an anomalous increase in non-ESRD-related drug costs in 2019 compared with prior years.
- 37 To determine total reported costs for audited facilities (which CMS did not publish in regulation), we multiplied 2018 average total cost 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.
- 38 As a result of rebasing, in 2014, CMS reduced the base payment rate by \$8.16 to \$239.02.
- 39 In 2019, there was an anomalous increase in non-ESRD-related drug costs for facilities associated with a dialysis organization compared with prior years.

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