



Medicare Payment
Advisory Commission

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Attention: CMS-1846-P

Dear Dr. Oz:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury Dialysis (AKI) Payment, and ESRD Quality Incentive Program," *Federal Register* 91, no. 122, pp. 38784-38875 (June 26, 2026). We appreciate CMS's ongoing efforts to administer and improve the Medicare program, particularly given the many competing demands on the agency's staff.

In this letter, we comment on CMS's proposals to:

- [Rebase and revise the ESRD bundled \(ESRDB\) market basket;](#)
- [Expand the low-volume payment adjustment \(LVPA\);](#)
- [Include oral-only phosphate binders in the ESRD prospective payment system \(PPS\) payment bundle as of January 1, 2027;](#)
- [Increase the home and self-dialysis training add-on payment adjustment; and](#)
- [Modify the payment for pediatric beneficiaries with ESRD on dialysis.](#)

We also comment on CMS's request for information on:

- [Approaches to strengthen care continuity and expand beneficiary choice of renal dialysis services that could be considered palliative in nature for beneficiaries approaching end of life, and](#)
- [Approaches to increase home dialysis use.](#)

Rebasing and revising the ESRD bundled market basket

The ESRD bundled (ESRDB) market basket forecasts how much providers' costs would change in future years if the quality and mix of inputs they use to furnish care remained constant. For calendar year (CY) 2027, CMS proposes to:

- rebase the current ESRDB market basket (which is currently based on 2020 cost reports) by updating the cost category weights using 2024 cost reports submitted by freestanding ESRD facilities, the U.S. Census Bureau's 2022 Services Annual Survey (SAS), and the Bureau of Economic Analysis's 2017 Benchmark Input-Output (I-O) data.¹
- revise the ESRDB market basket by changing cost categories and selected wage and price proxies that assess the rate of price change for each cost category. Wage and price proxies that CMS proposes to use include U.S. Bureau of Labor Statistics (BLS) indexes (Producer Price Index, Employee Cost Index, and Consumer Price Index).
- update the labor-related share of the base payment rate from 55.2 percent to 63.5 percent.

According to CMS, most 2024 Medicare cost reports submitted by one large dialysis organization (LDO) misreported chain designation, resulting in incorrect "Administrative & Other" net expenses. CMS outlines how the agency corrected this error before deriving the costs to rebase and revise the ESRDB market basket.

Comment

The Commission generally supports periodic rebasing of the ESRDB market basket using the most recent and accurate data available. However, we reiterate prior comments about the importance of auditing the cost reports that dialysis facilities submit to CMS and adjusting facilities' reported costs to reflect audit findings.² Ensuring the accuracy of the cost reports is important for payment accuracy and promoting beneficiaries' access to care given that the ESRDB market basket and ESRD PPS's payment adjustment factors are both derived from this source. Moreover, the Commission uses ESRD cost reports to calculate the fee-for-service (FFS) Medicare margin, which is considered (along with other factors) when assessing the adequacy of Medicare's payments for dialysis services. If the costs reported on Medicare cost reports are understated, the Medicare margin calculated using that cost data will be overstated, whereas if costs are overstated, the Medicare margin will be understated.

¹ Both the 2022 SAS and 2017 I-O data will be inflated to 2024 levels.

² Medicare Payment Advisory Commission. 2022. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system for CY 2023. https://www.medpac.gov/wp-content/uploads/2022/08/08192022_ESRD_CY2023_MedPAC_COMMENT_SEC.pdf.

It has been more than 10 years since ESRD cost reports were audited in 2015, and that audit concluded that dialysis facilities had included costs that Medicare does not allow.³ As described in CMS's ESRD PPS proposed rule for CY 2022, 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.⁴ 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. In the Commission's March 2022 report to the Congress, we estimated that \$147.5 million in unallowable costs represents about 4 percent of reported costs in 2018.⁵ If 4 percent of reported costs are unallowable, the estimated aggregate Medicare margin would be understated by nearly 4 percentage points.

In the proposed rule for CY 2027, CMS states that an LDO's misreported chain designation in the 2024 Medicare cost reports resulted in the under reporting of "Administrative & Other" net expenses.⁶ When we replicate CMS's methodology for correcting the 2024 dialysis facility cost reports for the LDO's error, we estimate that the aggregate Medicare margin reported by the Commission for CY 2024 was overstated by approximately 2 percentage points.⁷ The continued occurrence of reporting errors in a substantial number of cost reports underscores the need for another audit.

Expanding the low-volume payment adjustment

The current low-volume payment adjustment (LVPA) applies to facilities with a median number of treatments over the last three cost-reporting periods of fewer than 4,000.⁸ The LVPA has two tiers: dialysis facilities that furnish fewer than 3,000 treatments receive a payment adjustment of 28.9 percent, while those that furnish 3,000 or more treatments but fewer than 4,000 treatments receive a payment adjustment of 18.3 percent. The ESRD PPS also includes a rural payment adjustment, which increases a facility's base rate by 0.8 percent and applies to all facilities located in rural areas, regardless of treatment volume or proximity to other dialysis facilities.

³ 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. A contractor performed cost audits of these ESRD facilities in September of 2015. All audits were completed by September of 2018.

⁴ CMS's Office of the Actuary (OACT) selected a sample of 1,479 freestanding ESRD facilities from five large dialysis organizations (as defined by OACT) for the cost audit. CMS published results of their audit in the ESRD proposed rule for calendar year 2022 for 1,395 of the 1,479 ESRD facilities that had complete Healthcare Cost Report Information System (HCRIS) data (that is, containing both pre-and post-audit information).

⁵ Our estimate assumed 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.

⁶ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2026. Medicare program; CY 2027 changes to the end-stage renal disease (ESRD) prospective payment system, acute kidney injury dialysis (AKI) payment, and ESRD Quality Incentive Program. *Federal Register* 91, no. 122 (June 26): 38784–38875.

⁷ The CY 2024 FFS Medicare margin for freestanding dialysis facilities of 4.5 percent that was published in our March 2026 report to the Congress was calculated using the cost report data as submitted by ESRD facilities and available to the Commission at that time ([Chapter 5: March 2026 Report to the Congress: Medicare Payment Policy](#)).

⁸ A facility's treatment volume is the sum of the number of treatments furnished by a dialysis facility and that of other facilities under common ownership within 5 road miles or less.

CMS proposes to expand the LVPA in CY 2027 to a six-tiered adjustment for facilities with 8,000 or fewer treatments and apply a budget-neutrality factor of 0.98898. The proposed adjustment factors for the six tiers are 36.8 percent, 24.9 percent, 17.3 percent, 12.0 percent, 8.0 percent, and 0.50 percent for facilities with 0 to 2,999 treatments, 3,000 to 3,999 treatments, 4,000 to 4,999 treatments, 5,000 to 5,999 treatments, 6,000 to 6,999 treatments, and 7,000 to 7,999 treatments, respectively.

CMS provides several justifications for proposing a revised definition of low-volume facilities. First, the agency finds in dialysis facility cost reports from 2022 through 2024 that payments exceed costs for facilities with fewer than 10,000 treatments per year, “suggesting that cost differentials extend beyond the current LVPA threshold of 4,000 treatments.” Second, CMS notes that recent closures in ESRD facilities occurred disproportionately among small facilities. Third, the agency shows empirically via a facility-level regression analysis that furnishing fewer than 8,000 treatments per year is associated with higher costs per treatment.⁹

CMS also proposes extending the LVPA to treatments furnished to pediatric patients on dialysis. The agency does not propose any changes to the rural payment adjustment.

Comment

The agency’s expanded six-tier LVPA proposal is an improvement over current policy, as it will better align Medicare payments with facility costs. The Commission’s analyses have repeatedly found a statistically significant relationship under the ESRD PPS between the total number of treatments and cost per treatment, with total cost per treatment increasing for facilities furnishing fewer total treatments. While we support CMS’s proposal to revise the threshold for the LVPA adjustment to fewer than 8,000 treatments per year, and maintain budget neutrality, the Commission recommended replacing the current LVPA and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment.¹⁰ CMS’s current and proposed LVPA do not ensure that only isolated low-volume facilities receive the LVPA. Neither the LVPA nor the rural adjustment accurately targets facilities that are both critical to preserving beneficiary access and have high costs warranting a payment adjustment. Increasing the LVPA threshold, as proposed, may direct additional payments to facilities that are not isolated.

Include oral-only phosphate binders in the ESRD PPS payment bundle as of January 1, 2027

Per the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Medicare began a PPS in 2011 for outpatient dialysis services that expanded the prospective

⁹ The regression uses dialysis facility cost reports from 2022 through 2024 and controls for year, ownership, wage index, rurality, region, Medicare percent, home dialysis percent, pediatric share, and average non-LVPA payment adjustment multiplier. Facility size is specified using the natural logarithm for total treatments and included both linear and quadratic terms.

¹⁰ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

payment bundle to add (1) Part B ESRD drugs, laboratory tests, and other ESRD items and services that were previously billable separately and (2) Part D ESRD oral-only drugs—calcimimetics and phosphate binders. CMS delayed including ESRD oral-only drugs into the ESRD PPS to give facilities additional time to make operational changes and logistical arrangements to furnish these products to their patients. In addition, several statutory changes precluded CMS from including ESRD oral-only drugs (phosphate binders) prior to January 1, 2025.¹¹

Per regulatory and statutory requirements, CMS has paid for phosphate binders in 2025 and 2026 under the ESRD PPS using a transitional drug add-on payment adjustment (TDAPA). Under this TDAPA, CMS pays dialysis providers based on the number of units furnished at each product's average sales price (ASP), plus a fixed monthly payment of \$36.41 to account for providers' operational costs.¹²

Beginning January 1, 2027, CMS proposes (after a two-year TDAPA period) to include phosphate binders in the bundled payment. The agency considered a three-year TDAPA period (as was implemented for calcimimetics) but said that:

“We did not propose to continue TDAPA for a third year after we evaluated utilization data during the first year of TDAPA and met with several interested parties through public meetings where they recommended incorporation this year.”¹³

To calculate the increase to the ESRD PPS base rate to account for the cost of phosphate binders, CMS proposes to:

- Determine total phosphate binder utilization using claims submitted by dialysis facilities to CMS between April 1, 2025, and July 31, 2026.
- Use the most recent calendar quarter of ASP data (the fourth quarter of 2026) to price each phosphate binder according to its ASP, which is how the agency paid for the products under the TDAPA policy in 2025 and 2026.
- Multiply the phosphate binder expenditure amount by 1.06 to account for facilities' operational cost in furnishing phosphate binders.¹⁴

¹¹ Because an injectable equivalent of the oral calcimimetic was approved by the FDA in 2017, injectable and oral calcimimetics qualified for a transitional drug add-on payment under the ESRD PPS between 2018 and 2020. As of 2021, CMS included all calcimimetics in the PPS bundle and accounted for the calcimimetics' cost by adding \$9.93 to the base rate.

¹² CMS derived the fixed-rate addition of \$36.41 based on the weighted average of Medicare expenditures for all phosphate binders used in a month under Part D, using utilization patterns in 2023 among Part D-eligible beneficiaries. According to the agency, the monthly fixed-rate addition approximates 6 percent of ASP.

¹³ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2026. Medicare program; CY 2027 changes to the end-stage renal disease (ESRD) prospective payment system, acute kidney injury dialysis (AKI) payment, and ESRD Quality Incentive Program. Proposed rule. *Federal Register* 91, no. 122 (June 26): 38784–38875.

¹⁴ CMS notes that the operational costs for phosphate binders include costs associated with storage, distribution, staffing, and administrative expenses unique to the high-volume, multi-product nature of phosphate binder therapy.

- Calculate an average per treatment cost (in 2027 dollars) by dividing total phosphate binder expenditures by the total number of hemodialysis-equivalent treatments between April 1, 2025, and July 31, 2026.¹⁵

Based on the above methodology, CMS proposes to increase the PPS base rate by \$15.96 to account for phosphate binders' cost.

Comment

We reiterate our comment supporting payment of oral-only ESRD drugs under the ESRD PPS:¹⁶

- Their inclusion in the ESRD PPS payment bundle is intended in part to encourage providers to better manage drug therapy and improve efficiency. Although both CMS's and the Commission's analyses show that the ESRD PPS affected use of certain ESRD-related services, particularly the provision of drugs paid under the bundle, the agency's claims-based monitoring program has revealed no sustained decline of beneficiary health status from January 2010 through December 2023^{17, 18}
- Shifting coverage of ESRD-related drugs from Part D to Part B improves access to these medications for beneficiaries who lack Part D coverage or have coverage less generous than the Part D standard benefit.
- A prior Commission analysis showed that price competition within the erythropoiesis-stimulating agent and vitamin D therapeutic classes increased post-inclusion in the ESRD PPS bundle.¹⁹

Our comments focus on CMS's proposed method for determining the one-time addition to the ESRD PPS's base rate to account for the cost of phosphate binders and including associated operational costs into this addition. The one-time addition to the bundled payment should ensure access to high-quality services for beneficiaries and affordability of care for beneficiaries and taxpayers.

First, the cost of phosphate binders is determined by two factors, utilization and price. To determine utilization, CMS could align its methodology for determining the one-time addition to the ESRD PPS base rate for phosphate binders with the methodology the Congress specified in MIPPA for establishing the ESRD PPS. Specifically, MIPPA required that the Secretary use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization. Thus, to establish the 2011 ESRD PPS base rate, the agency evaluated data from 2007, 2008, and 2009 and determined that utilization from a

¹⁵ CMS would reduce the average per treatment amount by 1 percent to account for the outlier policy, since phosphate binders would be an ESRD service eligible for outlier payments beginning January 1, 2027.

¹⁶ Medicare Payment Advisory Commission. 2024. MedPAC's comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2025. August 22. https://www.medpac.gov/wp-content/uploads/2024/08/0822024_MedPAC_ESRD_PPS_CY2025_comment_v3_SEC.pdf.

¹⁷ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2024. *ESRD prospective payment system claims-based monitoring program*. Baltimore, MD: CMS.

¹⁸ Medicare Payment Advisory Commission. 2026. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁹ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

single year (2007) resulted in the lowest average payment amount per treatment, which reflected the lowest utilization of ESRD services. In our comment letter to CMS about incorporating calcimimetics in the bundled payment in CY 2021, we suggested such an approach because:

“Bundled payment encourages judicious consideration of the items and services provided to dialysis patients and cost-conscious decision making. Historically, the implementation of PPSs in Medicare has been characterized by providers quickly reducing use of services in the payment bundle. Because payments rates are not immediately adjusted, periods of “overpayment” allow providers to benefit from the change in practice patterns; however, the Medicare program does not realize savings until the payment rate is adjusted.²⁰ We saw this pattern in the ESRD PPS when the ESRD bundle was introduced in 2011. Because of the decline in the use of ESRD drugs during the initial years of the ESRD PPS, the Congress required that CMS rebase (lower) the outpatient dialysis payment rate effective 2014. Consequently, when calculating the addition to the base rate to account for calcimimetics, we strongly believe that CMS should use the year that results in the lowest average payment amount per treatment for these drugs to minimize overestimates of use under the bundle.”²¹

As for price data, CMS could use ASP pricing data for phosphate binders from the calendar quarter (during the TDAPA period) that would result in the lowest total expenditures for these drugs. Furthermore, CMS should consider whether the following factors will make it likely that the increase to the bundled payment in CY 2027 will exceed providers’ costs: (1) According to the Food and Drug Administration (FDA), an authorized generic of the brand-name phosphate binder Auryxia became available in March 2025;^{22, 23} (2) the FDA approved a generic alternative of Auryxia in March 2026;²⁴ and (3) one of the LDOs markets a phosphate binder—Velphoro—in the United States for which generic alternatives are not yet available.²⁵ Based on the proposed rule’s drug utilization and ASP pricing data, Velphoro accounts for approximately 73 percent of the proposed increase to the PPS’s base rate. The utilization and pricing experience from the TDAPA period that CMS proposes to use for incorporating phosphate binders into the ESRD PPS bundle may be overestimated given incorporating phosphate binders into the ESRD bundle will incentivize providers to

²⁰ Medicare Payment Advisory Commission. 2013. Comment letter on CMS’s proposed notice entitled “Medicare Program: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.” August 30.

²¹ Medicare Payment Advisory Commission. 2020. MedPAC’s comment on CMS’s proposed rule on the end-stage renal disease payment system for CY 2021. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09022020_esrd_cy_2021_medpac_comment_v2_sec.pdf.

²² Food and Drug Administration. 2026. Search of National Drug Code directory for non-proprietary name “ferric citrate.” Accessed July 22. https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm.

²³ Akebia Therapeutics Inc. 2025. Form 10-Q submitted to the Securities and Exchange Commission for the quarterly period ended March 31, 2025. <https://ir.akebia.com/static-files/3bb29121-4bde-4b9f-9051-1284b83b9fc1>.

²⁴ Food and Drug Administration. 2026. Search of National Drug Code directory for drug name “ferric citrate.” Accessed July 22. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

²⁵ Fresenius Medical Care. 2025. Form 20-F submitted to the Securities and Exchange Commission for the fiscal year ending December 31, 2025.

deliver this care more efficiently and the entry of generic alternatives provides opportunity to lower costs.

As a point of reference, the Commission's analysis found that, in 2023, clinicians prescribed phosphate binders with generic alternatives to approximately 80 percent of beneficiaries on dialysis under Part D. If the share of beneficiaries for whom phosphate binders with generic alternatives prescribed during the TDAPA period is substantially lower than 80 percent, it could suggest that the TDAPA's financial incentives affected providers' prescribing patterns by increasing the use of higher-priced, brand-name phosphate binders.

Second, CMS should not include in the ESRD PPS base rate an additional payment to account for operational costs associated with phosphate binders. As CMS noted in the proposed rule, "...some operational costs associated with furnishing oral drugs is already included in the ESRD PPS base rate."²⁶ In addition, the two-year TDAPA period likely gave dialysis providers sufficient time to gain experience furnishing phosphate binders, eliminating the need to continue accounting for the associated operational costs once these products are incorporated into the ESRD PPS bundle.

However, if the agency elects to increase the ESRD PPS base rate to account for phosphate binders' operational cost, CMS should proceed with its proposed method—multiplying the direct drug expenditure amount, which is derived based on each drug's ASP.²⁷ According to the agency, doing so would result in a total operational cost (added to the base rate) of \$16.2 million. CMS's proposed approach would result in less financial burden to beneficiaries and taxpayers compared to CMS's alternative approach that is based on the TDAPA's monthly fixed rate addition of \$36.41 to cover phosphate binders' operational cost and would result in a total operational cost of \$25.9 million included in the base rate.

Increase the home and self-dialysis training add-on payment adjustment

Beginning January 1, 2027, CMS proposes to increase the home and self-dialysis training add-on payment adjustment to \$138.22 per treatment from the current amount of \$95.60 per treatment. The training add-on is only intended to cover the labor-related costs for home and self-dialysis training, as the ESRD PPS base rate includes payment for all other costs associated with furnishing renal dialysis services. CMS will continue its policy of paying an add-on for 15 training treatments for peritoneal (PD) and 25 training treatments for home hemodialysis (HHD).

The current training payment adjustment of \$95.60 was last updated in the CY 2017 ESRD PPS final rule and was based on:

²⁶ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2026. Medicare program; CY 2027 changes to the end-stage renal disease (ESRD) prospective payment system, acute kidney injury dialysis (AKI) payment, and ESRD Quality Incentive Program. Proposed rule. *Federal Register* 91, no. 122 (June 26): 38784–38875.

²⁷ As we noted in our comment letters on the CY 2025 and 2026 ESRD proposed rules, the Commission does not support linking phosphate binders' monthly operational cost to a drug's ingredient cost.

- An assumed 2.66 hours of training time by a registered nurse (RN) at a wage equal to the 2017 national mean (\$35.93).
- An estimated average training treatment time of 2.66 hours that assumes 2 hours per PD training treatment and 4 hours per HHD training treatment, weighted by the share of PD (67 percent) and HHD training treatments (33 percent) (2.66 hours = $((0.67 \times 2 \text{ hours}) + (0.33 \times 4 \text{ hours}))$).²⁸
 - CMS's estimate of the length of a PD and HHD treatment session was not empirically derived; rather it is based on "[the] sources we researched indicated 4 hours is a clinically appropriate length of time for HD and 2 hours is a clinically appropriate length of time for a PD treatment. The Kidney Disease Outcomes Quality Initiative guidelines and educational material from various patient advocacy groups are examples of these sources."²⁹

The proposed training add-on payment rate per treatment of \$138.22 reflects a 2027 national mean RN wage (\$51.96) and the average training treatment time of 2.66 hours (last updated in 2017).

CMS states that because the ESRD PPS is not a cost-based system, and cost report data may not reliably isolate the marginal cost of training, the agency does not believe it is appropriate to base the training add-on payment amount directly on these data. Finally, CMS proposes to apply a budget-neutrality factor to the ESRD PPS base payment rate to offset the increase in the training add-on payment and to continue its policy of paying the same add-on payment for PD and HHD training.

Comment

The Commission believes that beneficiaries with ESRD who require dialysis should have access to all dialysis modalities, including in-center hemodialysis, PD, and HHD. Each modality has advantages and disadvantages, and no single approach is appropriate for every patient. For some patients, home dialysis offers advantages over in-center dialysis, including greater patient satisfaction, improved health-related quality of life, and fewer transportation challenges. The Commission urges CMS to annually update the training

²⁸Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model. Final rule. *Federal Register* 81, no. 214: 77834-77969.

²⁹Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2016. Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model. Final rule. *Federal Register* 81, no. 214: 77834-77969.

add-on payment to reflect current labor cost estimates and the average time per treatment needed to train beneficiaries. Based on CMS's current method to derive the add-on training payment, we encourage the agency to:

- Update the add-on payment adjustment each year using publicly available BLS Occupational Employment and Wage Statistics data so that the add-on payment reflects trends in wage growth.
- Develop a process to empirically derive the share of treatments that are PD versus HHD and the average length of a training session. For example, CMS could derive the share of training treatments by modality from Medicare claims data. To derive the average length of a training session, CMS should explore opportunities to collect data from providers via the ESRD cost reports, ESRD PPS claims, or the ESRD Quality Reporting System. We note that CMS currently requires facilities to report “time on machine” data (the number of minutes between the start and end of hemodialysis treatment) on ESRD PPS claims for in-center hemodialysis treatments as well as any training or retraining treatments that are provided in-center.

CMS's proposal to maintain a single payment rate is consistent with the ESRD PPS's structure, as PD and HHD are paid the same for adult beneficiaries, and avoids creating financial incentives that could influence modality selection. A single training payment rate is consistent with the Commission's long-held position that Medicare should pay similar rates for similar care. We support CMS's proposal to keep the increase to the training add-on budget neutral.

Payment for pediatric beneficiaries with ESRD on dialysis

Since the ESRD PPS was implemented in 2011, Medicare pays for pediatric beneficiaries using a wage-adjusted PPS base rate that is adjusted for two age categories (under age 13 or age 13 to 17) and two dialysis modalities (PD or hemodialysis). The base payment rate for adults is adjusted for the following patient-level characteristics: age; two body measurement variables (body surface area (BSA) and body mass index (BMI)); four comorbidities (pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome); and onset of dialysis. Currently, under the ESRD PPS, CMS uses a two-equation regression model—one regression model at the facility level using 2012 and 2013 cost report data and a second model at the patient level using 2012–2013 ESRD PPS claims—to estimate the case-mix and facility-level adjustments to the base payment rate for pediatric and adult beneficiaries.³⁰

For calendar years 2024 through 2026, CMS applied a budget-neutral pediatric transitional add-on payment adjustment, equaling 30 percent of the per treatment payment amount, for dialysis services provided to pediatric patients. The agency implemented this payment adjustment to bring Medicare payments for dialysis services

³⁰ The Commission's Payment Basics series provides more information about Medicare's method of paying for outpatient dialysis services (see “Outpatient Dialysis Services Payment System” in our Payment Basics series, available at https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_25_dialysis_FINAL_SEC.pdf.)

furnished to pediatric patients more in line with their estimated relative costs for a three-year period until the agency could conduct additional analysis of cost report and ESRD PPS claims data. In 2024, the pediatric beneficiaries with ESRD represented approximately 0.16 percent of total dialysis treatments.

Beginning in January 2027, CMS proposes to use more recent (2022–2023) ESRD cost and claims data to update the pediatric case-mix adjusters using the same general methodology it last used to update both the pediatric and adult case-mix adjusters—a two-equation regression model. The agency does not propose updating the adult case-mix adjusters. As stated above, the agency also proposes to begin applying the LVPA to treatments furnished to pediatric beneficiaries by dialysis facilities that meet the low-volume criteria. According to CMS, these two proposed changes would result in roughly the same expected spending on pediatric beneficiaries, but with payments better targeted to lower-volume ESRD facilities with higher anticipated resource use. These two changes are proposed on a budget-neutral basis.

Comment

CMS should recalibrate both the pediatric and adult case-mix adjusters simultaneously using more recent data. We are concerned about the accuracy of the ESRD PPS if the agency updates the pediatric adjusters without updating the adult adjusters. Because the pediatric payment methodology is related to the adult ESRD PPS framework, updating pediatric case-mix adjustments using 2022 and 2023 data while leaving adult adjustments based on 2012 and 2013 data would create a payment system in which different beneficiary populations are calibrated using different periods of resource use. A newer pediatric model may capture higher labor costs, changing staffing patterns, newer treatment protocols, different supply and drug costs, and post-pandemic practice changes while the adult case-mix coefficients would continue to reflect the resource relationships observed a decade earlier.

As we have said in prior comment letters and in our June 2020 report to the Congress, CMS should develop pediatric and adult payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle. Given the availability of cost data for the full PPS payment bundle, it is no longer necessary to use pre-2011 service categories when developing the adjustment factors. The distribution of average treatment cost across facilities is quite likely to be different from the distribution of payments for separately billable services across patients, and combining the two factors estimated on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. We have said repeatedly that continuing to estimate payment adjusters using a two-equation regression methodology in which the adjusters are derived by multiplying coefficients from the facility-level and patient-level regressions (with different bases) can diminish the accuracy of the combined coefficients.

We also reiterate our concerns about the ESRD PPS's payment adjusters for comorbidities and body size for adult beneficiaries. We have previously said that the comorbidity adjusters may result in undue burden on patients or the provision of unnecessary diagnostic procedures for the facility to be eligible for the payment adjustment and that

the agency should align the claims used to estimate the comorbidity adjustment factors with the claims used to identify eligibility for the adjustment.³¹ Regarding the body size adjusters, we have said that CMS should address the inherent correlation between BSA and BMI (calculated based on patient height and weight) by jointly estimating the association of BSA and BMI with treatment cost. The Commission's analyses have found that their values are correlated such that patients with low BMI also tend to have low BSA, and that these variables have a joint effect on treatment costs that is different from the sum of independent effects as currently implemented.

Approaches to strengthen care continuity and expand beneficiary choice of renal dialysis services that could be considered palliative in nature for beneficiaries approaching end of life

CMS is exploring whether refinements to payment policy could improve access to palliative dialysis while maintaining the integrity of the ESRD PPS and hospice per diem payments, and safeguarding against duplicative payment and program integrity risks. CMS solicits public comment on the definition of palliative dialysis; criteria on which to base beneficiary eligibility for palliative dialysis; appropriate delineation of responsibilities and coordination of services across dialysis facilities, hospice providers, and home health agencies; and considerations for payment policy, program integrity safeguards, and potential models and policy approaches.

Comment

In the hospice proposed rules for fiscal years 2024 and 2025, CMS raised questions about access under the hospice benefit to certain high-cost complex services that may be palliative for some hospice beneficiaries—specifically, dialysis for beneficiaries with ESRD and radiation, blood transfusions, and chemotherapy for beneficiaries with cancer. Hospices are responsible for the cost of all services that are reasonable and necessary for palliation of the patient's terminal condition and related condition, and Medicare's hospice payment system pays a per diem rate regardless of services provided. Our June 2026 report to the Congress sought to examine this issue.³² We reviewed relevant literature; summarized findings from interviews with clinicians, hospice providers, dialysis providers, and family caregivers; and analyzed available Medicare data (claims, cost reports, and hospice enrollment data) to study the role of, and the access that beneficiaries currently have to, certain high-cost complex services that may be palliative for some patients who are in hospice or who wish to transition to end-of-life care, including dialysis for beneficiaries with ESRD. We discussed several approaches that policymakers could consider to improve the accuracy of the hospice payment system for beneficiaries with ESRD or cancer who receive certain complex palliative services.

³¹ CMS could use only claims submitted by dialysis facilities both to estimate the comorbidity coefficients and to identify treatments eligible for a comorbidity adjustment, or use claims submitted by all providers both to estimate the comorbidity coefficients and to identify treatments eligible for a comorbidity adjustment.

³² Medicare Payment Advisory Commission. 2026. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC

While there may be other candidates for palliative dialysis beyond the hospice population, our report focuses on the potential palliative role of dialysis in hospice for some beneficiaries who had been receiving maintenance dialysis. Interviewees commonly reported three reasons for furnishing these services in hospice, including providing symptom relief, easing the transition to hospice, or helping patients reach specific goals (e.g., attending a family wedding). Interviewees indicated that some patients with ESRD do not enroll in hospice or enroll very near the end of life due to concerns about ceasing dialysis. Interviewees also reported that the cost of dialysis generally exceeds the Medicare hospice daily payment rate (for routine home care), though the cost of providing the services varied by a hospice's ability to negotiate rates and execute contracts with dialysis facilities. We also learned from our interviews that some dialysis providers may be reluctant to furnish palliative dialysis (e.g., fewer treatments per week) under the ESRD benefit because of its potential to affect the facility's clinical performance under the ESRD PPS's Quality Incentive Program.

Consistent with these interview findings, our data analyses showed that Medicare beneficiaries with ESRD receiving maintenance dialysis who are near the end of life are less likely than other terminally ill beneficiaries to enroll in hospice. In 2024, 31 percent of Medicare decedents with ESRD enrolled in hospice compared with 53 percent of all Medicare decedents. Further, although hospice use among decedents with ESRD has grown, the rate of growth is lower compared with that of all Medicare decedents. Hospice cost-report data do not break out dialysis costs and hospice claims do not include information on hospices' provision of dialysis, so the share of hospices that provide dialysis and the share of patients who receive dialysis under the hospice benefit is unknown. FFS claims data show a small share (13 percent) of Medicare decedents with ESRD who enrolled in hospice in 2019 received dialysis that was paid for outside the hospice benefit, presumably because the hospice and dialysis facility considered it to be unrelated to the terminal condition.

Policymakers concerned about hospice beneficiaries' access to certain complex palliative services, including dialysis, could consider a number of approaches. The Commission considered these three approaches, each one presenting trade-offs. First, to learn more about beneficiary access to such services before considering the need for modifications to the hospice payment system, CMS could, for a limited period, collect data from hospice providers about the use of certain high-cost complex palliative services. Next, if policymakers determine that changes are warranted to improve payment accuracy for hospice patients receiving complex palliative services, the hospice PPS could be modified in a budget-neutral manner (funded by a percentage reduction to the hospice base rate for all providers) via (1) an outlier policy, or (2) add-on payments for the provision of certain high-cost palliative services. An outlier policy would direct additional payments to hospice providers who incur higher costs for providing certain palliative services. This approach would maintain the bundled nature of the hospice PPS while improving payment accuracy and ensure that financial risk is shared between hospice providers and the Medicare program. However, some stakeholders might view outlier payments, which pay for only a portion of the additional costs associated with high-cost services, as insufficient. Add-on payments for the provision of certain high-cost palliative services would increase incentives for hospices to furnish these services to beneficiaries. But this

approach would also create incentives to furnish costly services even when they are not palliative or not aligned with the patient's plan of care. Limiting the amount of add-on payments a hospice could receive may, as one example, help safeguard against the possibility of adverse financial incentives.

As an alternative to changing the hospice PPS, policymakers could consider a voluntary transitional program through the CMS Innovation Center (CMMI) that would offer hospice enrollees the option to receive certain services such as dialysis for some transitional period, or up to a specified number of treatments, paid for outside of the hospice benefit. Clinicians we interviewed told us that some beneficiaries with ESRD who are dependent on dialysis and wish to enroll in hospice may be dissuaded from doing so because immediately ceasing treatment would be likely to result in death in a short period. A voluntary transitional program could help ease the transition to hospice for dialysis-dependent beneficiaries who are near the end of life and wish to enroll in hospice. Although several CMMI models have included flexibility to offer transitional concurrent care (e.g., certain conventional treatments) to hospice enrollees in certain circumstances, the use of concurrent care has not been the models' primary focus. A transitional program for beneficiaries with ESRD receiving maintenance dialysis could give the Secretary the opportunity to, in a limited fashion, directly test transitional concurrent care for hospice enrollees for services where access concerns have been raised by stakeholders. In developing a transitional model, the agency would need to consider, among other design issues, how to structure a transitional program, how to promote close collaboration between dialysis providers and the hospice physician, and how to minimize the potential for unintended financial incentives or undermining the hospice benefit criteria.

Request for information about increasing home dialysis use

CMS is soliciting comment on potential approaches that could increase home dialysis utilization among Medicare FFS beneficiaries. CMS seeks public comment on policy, payment, operational, and regulatory changes within the ESRD PPS, and in coordination with other Medicare payment systems, when relevant, that could increase the percentage of incident, non-pediatric, non-MA beneficiaries with ESRD initiating dialysis on a home modality and remaining on that modality. The agency is also soliciting comments about changes to the ESRD PPS to support greater flexibility for patients and nephrologists to use alternative dialysis schedules.

Comment

The Commission applauds the agency's commitment to promoting access to home dialysis among beneficiaries with ESRD. As we have already noted, for appropriate patients, home dialysis may offer greater flexibility and independence, higher patient satisfaction, improved health-related quality of life, and fewer transportation challenges than in-center hemodialysis.

To treat ESRD, beneficiaries on dialysis receive care from two principal providers: (1) the physicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary's plan of care and (2) facilities (i.e., dialysis providers) that

furnish dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Both dialysis providers and physicians who treat beneficiaries with ESRD on dialysis have an important role in educating beneficiaries about renal treatment options, including home dialysis and transplantation.

In 2012, the Commission convened a panel of clinicians who treat patients on dialysis and a patient representative to explore the pros and cons of home dialysis and more frequent hemodialysis. Although this panel was convened more than a decade ago, many of its findings are likely still relevant to the current use of home dialysis and alternative renal modalities:

- Panelists said that patient motivation and, for home patients, having a supportive partner, are two important factors associated with the successful use of more frequent hemodialysis. They discussed the issues and trade-offs associated with patients deciding to undergo more frequent hemodialysis and home dialysis. On the one hand, there is greater independence, flexibility, and satisfaction among patients undergoing home dialysis. On the other hand, some patients might prefer in-center dialysis because of the greater social interaction and support they receive. For home patients, lifestyle issues— including storage of equipment and supplies—affect their choice of home versus in-center dialysis. In addition, some patients lack a partner at home to assist them with home hemodialysis. And, because of the greater time commitment of more frequent dialysis compared with three times weekly, some patients and their partners may experience fatigue and burnout.
- Panelists talked about the importance of providers and patients discussing home versus in-center treatment and the alternatives for patients with ESRD, including transplantation, PD, and more frequent hemodialysis. Researchers have found patient counseling before starting dialysis is a strong determinant of choosing home-based methods. Panelists also discussed the lack of physician education and training in home dialysis and more frequent hemodialysis.³³

Medicare's payment and coverage policies have influenced the use of home dialysis. Researchers have concluded that the ESRD PPS, which began in 2011, is associated with an overall increase in the use of home dialysis. According to the Commission's analysis, home dialysis has steadily increased from 9 percent per month in 2011 (the first year of the ESRD PPS) to 17 percent per month in 2023 and 18 percent per month in 2024.

Nonetheless, clinical and nonpayment factors also play an important role in many patients' decisions to initiate home dialysis and in the overall uptake of home dialysis.

³³ Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar13_ch06_appendix.pdf.

Some of the clinical and nonclinical factors affecting the use of home dialysis that the Commission discussed in its March 2018 report to the Congress include:³⁴

- *Patient characteristics and social circumstances.* Researchers have concluded that patients living in more affluent areas, areas with a lower share of people who are unemployed, and rural areas were more likely to use home dialysis. These researchers also reported lower home dialysis use among patients with comorbidities—including diabetes, coronary artery disease, heart failure, and peripheral vascular disease—and institutionalized patients. According to the Commission’s analysis, differences by race in home dialysis use have persisted over time: Although about 27 percent of FFS Medicare beneficiaries with ESRD on dialysis are Black, they represent only 23 percent of beneficiaries who dialyze at home.³⁵
- *Prior nephrology care.* The Commission and other researchers have shown that nephrology care before being diagnosed with ESRD increased the use of home dialysis.³⁶
- *Training of nephrologists.* Nephrology trainees have reported low and moderate levels of preparedness for managing patients on HHD and PD, respectively.³⁷ In addition, the education and experience of dialysis facilities’ staff may affect patients’ knowledge and perception of home dialysis.
- *Other factors.* For example, shortages of dialysate, the solution used in PD, have adversely affected the growth in the use of PD during the past decade.

Regarding any changes to the ESRD PPS that the agency considers that aim to promote home dialysis or alternative dialysis schedules, it is important to maintain the structure of the ESRD PPS and not create policies that will unbundle services covered under the ESRD PPS. We have repeatedly said that paying separately for new technologies (e.g., drugs and capital equipment) using an add-on payment under the ESRD PPS:

- undermines the integrity of PPS bundle;
- limits the competitive forces that generate price reductions among like services;

³⁴ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch6_sec.pdf.

³⁵ Lin, E., X. S. Cheng, K. K. Chin, et al. 2017. Home dialysis in the prospective payment system era. *Journal of the American Society of Nephrology* 28, no. 10 (October): 2993–3004.

³⁶ Gillespie, B. W., H. Morgenstern, E. Hedgeman, et al. 2015. Nephrology care prior to end-stage renal disease and outcomes among new ESRD patients in the USA. *Clinical Kidney Journal* 8, no. 6 (December): 772–780.

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

Medicare Payment Advisory Commission. 2004. *Report to the Congress: New approaches in Medicare*. Washington, DC: MedPAC.

³⁷ Gupta, N., E. B. Taber-Hight, and B. W. Miller. 2021. Perceptions of home dialysis training and experience among US nephrology fellows. *American Journal of Kidney Diseases* 77, no. 5 (May): 713–718 e711.

- can lead to overuse (to the extent clinically possible); and
- shifts financial burden from providers to the Medicare program, beneficiaries, and taxpayers.³⁸

The Commission has also said that broader payment models under a shared savings program that would hold both dialysis facilities and managing clinicians accountable for all the care furnished to their patients with advanced chronic kidney disease (CKD) and ESRD could incentivize home dialysis use and kidney transplantation by:

- holding providers accountable for the service utilization, financial, and quality outcomes of beneficiaries following kidney transplantation;
- holding providers accountable for the service utilization, financial, and quality outcomes of beneficiaries with advanced CKD (e.g., CKD stage 3B and CKD stage 4); and/or
- paying a bonus (e.g., through shared Medicare savings) for beneficiaries who are successfully maintained on home dialysis and kidney transplant.³⁹

Finally, Medicare payments for dialysis care under the physician fee schedule do not consistently incentivize physicians to prescribe home dialysis and might create modest incentives for certain physicians to prescribe in-center dialysis. Based on 2013 Medicare fee schedule data, the Government Accountability Office (GAO) found that the monthly capitated payment (MCP) rate for managing adult home patients was lower than the average payment and maximum payment for managing adult in-center patients.⁴⁰ GAO recommended that CMS examine Medicare policies for monthly payments to physicians to manage the care of patients on dialysis and revise them if necessary to ensure that these policies are consistent with CMS's goal of encouraging the use of home dialysis among patients for whom it is appropriate.

According to the 2026 physician fee schedule:

- The MCP payment rate for adult home patients (Healthcare Common Procedure Coding System (HCPCS) 90966) is equivalent to the MCP rate for adult in-center patients furnished two to three visits in a month (HCPCS 90961).

³⁸ Medicare Payment Advisory Commission. 2022. MedPAC comment letter on CMS's proposed rule on the end-stage renal disease payment system for CY 2023. https://www.medpac.gov/wp-content/uploads/2022/08/08192022_ESRD_CY2023_MedPAC_COMMENT_SEC.pdf.

Medicare Payment Advisory Commission. 2020. MedPAC comment letter on CMS's proposed rule on the end-stage renal disease payment system for CY 2021. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09022020_esrd_cy_2021_medpac_comment_v2_sec.pdf.

³⁹ Medicare Payment Advisory Commission. 2020. MedPAC's comments on the proposed ESRD Treatment Choices Model – MedPAC. <https://www.medpac.gov/medpacs-comments-on-the-proposed-esrd-treatment-choices-model/>.

⁴⁰ Government Accountability Office. 2015. *End-stage renal disease: Medicare payment refinements could promote increased use of home dialysis*. Washington, DC: GAO.

- The MCP payment rate for adult home patients (HCPCS 90966) is less than the MCP rate for adult in-center patients furnished four or more visits in a month (HCPCS 90960).

CMS could consider aligning the home dialysis MCP payments with the in-center MCP payments in a budget-neutral manner across the MCP codes.

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please contact Paul B. Masi, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amol S. Navathe', with a stylized flourish at the end.

Amol S. Navathe, M.D., Ph.D.
Chair