



August 19, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: File code CMS-1768-P

Dear Ms. Brooks-LaSure:

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; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" in the *Federal Register*, vol. 87, no. 123, pp. 38464–38586 (June 28, 2022). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2023, update the payment rate for services provided to individuals with acute kidney injury (AKI) when those services are furnished in ESRD facilities, address the ESRD Quality Incentive Program, and address the ESRD Treatment Choices Model. We appreciate your staff's ongoing efforts to administer and improve payment systems for ESRD, particularly considering the competing demands on the agency.

Our comments address the following provisions in the proposed rule:

- Updating the ESRD PPS base rate for calendar year (CY) 2023
- Rebasement and revising the ESRD market basket for CY 2023 and updating the labor-related share of the ESRD PPS base rate
- Implementing a permanent cap on decreases of the wage index
- Increasing the wage index floor
- Refining the ESRD PPS's outlier policy
- Revising the definition of an ESRD oral-only drug
- Request for information on payment for certain new ESRD drugs after the end of their transitional drug add-on payment adjustment (TDAPA) period

- Request for information on overarching principles for measuring healthcare quality disparities across CMS quality programs

Updating the ESRD PPS base rate for CY 2023

Per statutory requirements, CMS proposes to update the ESRD PPS base rate for CY 2023 by 2.4 percent. This update is based on the ESRD market basket increase factor (of 2.8 percent) reduced by a multifactor productivity adjustment (of 0.4 percent). The proposed CY 2023 ESRD PPS base rate is \$264.09, which is an increase of \$6.19 to the current base rate of \$257.90.¹

Comment

The Commission recognizes that CMS must provide the statutorily mandated payment update of the market basket minus the productivity adjustment. The Commission has concluded that this increase is warranted based on our analysis of payment adequacy. In our March 2022 report to the Congress, the Commission's assessment of the adequacy of Medicare's payments to freestanding ESRD facilities was generally positive.² (Our payment adequacy assessment includes beneficiary access, supply and capacity of providers, providers' access to capital, quality, and financial indicators for the sector.) The Medicare margin for freestanding ESRD facilities was 2.7 percent in CY 2020, and we project it will drop to 1.8 percent in CY 2022. Based on this assessment, the Commission recommended that, for 2023, the Congress should update the CY 2023 ESRD PPS base rate by the amount determined under current law.

Rebasing and revising the ESRD market basket for CY 2023

The ESRD 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 CY 2023, CMS is proposing to:

- rebase the current ESRD market basket (which is currently based on 2016 cost reports) by updating the cost category weights using 2020 cost reports submitted by freestanding ESRD facilities and data from the U.S. Census Bureau's Services Annual Survey.
- revise the ESRD market basket by adding additional cost categories and changing 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 52.3 percent to 55.2 percent (in part because the labor cost weight increases and the pharmaceutical cost weight decreases under the rebased and revised ESRD market basket).

¹ The update to the ESRD PPS base rate also reflects the application of the wage index budget-neutrality adjustment factor.

² Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Comment

The Commission generally supports periodic rebasing of the ESRD market basket using the most recent and accurate data that are available. At the same time, we have been cautious about using data from 2020, as COVID-19 has disproportionately affected dialysis beneficiaries and has had material effects on ESRD facilities' patient volume, revenues, and costs. However, both CMS's and the Commission's analyses of cost report data from freestanding ESRD facilities have found relatively consistent trends in the share of costs in cost categories (e.g., capital, labor, drugs, et cetera) between 2016 and 2020, suggesting that using 2020 freestanding ESRD cost report data for rebasing the cost weights of the market basket may be appropriate.

Consequently, CMS should proceed with rebasing the ESRD market basket using 2020 freestanding ESRD cost report data. However, we urge the agency to monitor the effects of COVID-19 on freestanding ESRD facilities' costs moving forward. CMS should consider rebasing the ESRD market basket more frequently (than every four years) if these trends change and the cost category weights no longer accurately represent freestanding ESRD facilities' costs. Such an approach appears aligned with CMS's point of view on the frequency that providers' market baskets are rebased:

*"Typically, a market basket is rebased every four to five years... We continually monitor the cost weights in the market baskets to ensure they are reflecting the mix of inputs used in providing services. We will update the weights more frequently than every four to five years if we believe it is warranted."*³

To better ensure accuracy, CMS's rebasing of the market basket should reflect the findings from the agency's most recent audit of freestanding ESRD facilities.⁴ Similar to prior audits of ESRD facilities' cost reports, CMS's most current audit found that cost reports have included costs that Medicare does not allow. 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.⁵ 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

³ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. FAQ—Market basket definitions and general information. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/info.pdf>.

⁴ 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 2018.

⁵ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2021. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. *Federal Register* 86, no 129 (July 9): 36322–36437.

unallowable costs represents about 4 percent of reported costs in 2018.⁶ If CMS does not adjust facilities' reported costs to reflect the audit findings, then the cost category weights that CMS derives to create the rebased ESRD market basket may be inaccurate.

In addition, we note that CMS's impact analysis in the proposed rule for CY 2023 suggests that updating the labor-related share of the base payment (to reflect the proposed 2020 labor-related cost share weights) will result in lower payments for low-volume facilities and facilities in rural areas. Because of the effect of the proposed rebasing on low-volume facilities and facilities located in rural areas, we reiterate the Commission's 2020 recommendation that the Secretary replace the ESRD PPS's current low-volume payment adjustment and the rural adjustment with a single payment adjustment—a low-volume and isolated adjustment—to better protect isolated, low-volume ESRD facilities that are critical to ensure beneficiary access.⁷

Implementing a permanent cap on decreases of the wage index

For CY 2023 and subsequent years, CMS is proposing to apply a 5 percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, an ESRD facility's wage index for a given calendar year would not be less than 95 percent of its final wage index for the previous year.

Comment

The Commission supports CMS's goal of promoting predictability and stability in ESRD PPS payments, including its budget-neutral proposals to cap the amount by which certain components can change in a given year. However, we reiterate our prior comments that any caps on the maximum annual change to wage indexes should apply not just to decreases but to increases as well.^{8,9}

⁶ 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 (see Chapter 6 of MedPAC's March 2022 report to the Congress, available at https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch6_SEC.pdf). Our estimate assumes audited facilities in the aggregate had average costs; 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.

⁷ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

⁸ Medicare Payment Advisory Commission. 2020. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2021. September 2. 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.

⁹ Medicare Payment Advisory Commission. 2022. MedPAC comment letter regarding the Medicare acute care hospital and long-term care hospital prospective payment systems for 2023. June 16. https://www.medpac.gov/wp-content/uploads/2022/06/06162022_FY2023_IPPS_LTCH_MedPAC_COMMENT_v2_SEC.pdf.

Increasing the wage index floor

For CY 2023 and beyond, CMS is proposing to increase the ESRD PPS wage index floor from 0.5 to 0.6. Currently, only Puerto Rico would be impacted by this proposal. The wage index floor of 0.5 has been in effect since January 1, 2019. Since 2011, the ESRD PPS wage index floor has ranged between 0.4 and 0.6. CMS lowered the floor from 0.6 to 0.4 between CY 2011 and CY 2015, maintained the floor at 0.4 between CY 2016 and CY 2018, and then increased the floor to 0.5 in CY 2019. According to CMS, increasing the wage index floor to 0.6 in CY 2023 “...*would be responsive to comments from interested parties, safeguard access to care in areas at the lowest end of the current wage index distribution, and be supported by data and analyses that support a higher wage index floor...*”¹⁰

CMS’s proposal to increase the ESRD wage index floor to 0.6 is derived from an analysis published in the agency’s CY 2019 rulemaking process for ESRD services that found the following:

- The wage index for the territory of Puerto Rico likely lies between 0.510 and 0.550. CMS derived these values by combining labor data from CY 2013 to CY 2015 ESRD facilities’ cost reports from Puerto Rico, augmented with wage information from the Bureau of Labor Statistics (BLS) specific to Puerto Rico.
- Any ESRD wage index values less than 0.5936 are considered statistical outliers. CMS derived this value from the distribution of CY 2018 wage index values.¹¹

Comment

The Commission reiterates our standing position that wage index floors and related policies (e.g., exceptions and reclassifications) distort area wage indexes.¹² In addition, the Commission asserts that the current wage index used in the ESRD PPS is flawed, in that it is based only on data from hospitals, rather than wage data for all of the health care providers in a given market.

As we stated in our letter of August 31, 2018, in place of using the unadjusted hospital wage index (plus a national floor) for ESRD facilities, CMS should establish an ESRD wage index for all ESRD facilities (not just those located in Puerto Rico) that:

- uses wage data representing all employers and industry-specific occupational weights,

¹⁰ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. Proposed Rule. *Federal Register* 87, no 123 (June 28): 38464–38586.

¹¹ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program; end-stage renal disease prospective payment system, 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 (DMEPOS) Competitive Bidding Program (CBP) and fee schedule amounts, and technical amendments to correct existing regulations related to the CBP for certain DMEPOS. *Federal Register* 83, no. 139 (July 19): 34304.

¹² Medicare Payment Advisory Commission. 2007. *Promoting greater efficiency in Medicare*. Washington DC: MedPAC.

- is adjusted for geographic differences in the ratio of benefits to wages,
- is adjusted at the county level and smooths large differences between counties, and
- is implemented so that large changes in wage index values are phased in over a transition period.¹³

The Commission continues to believe a wage index floor is not appropriate and opposes codifying a higher floor value. CMS states that a goal of the proposed floor is “...*providing increased payment to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicate...*”¹⁴ However, CMS’s analysis of data specific to Puerto Rico (2013 to 2015 ESRD cost reports and 2015 BLS data) shows that actual relative wages in Puerto Rico are likely between 0.51 and 0.55; setting a wage index floor at 0.6 would adjust payments to dialysis facilities beyond what is warranted by actual wages. To the extent that CMS has concerns about the accuracy of the unadjusted hospital wage index for Puerto Rico, the agency should update its analyses using the most recent cross-industry wage data from the BLS and set the Puerto Rico wage index based on that analysis instead of a floor set using the distribution of all area wage indexes.

Refining the ESRD PPS’s outlier policy

The outlier policy in the ESRD PPS partially reimburses facilities’ costs for certain patients that incur very high costs for items and services that were separately billable prior to the implementation of the ESRD PPS.¹⁵ The policy aims to distribute 1 percent of total spending to the highest-cost months of treatment by reimbursing 80 percent of costs above a specified threshold. Each year, CMS estimates the outlier threshold based on two values: (1) the average spending on separately billable services (referred to as the Medicare Allowable Payment (MAP) amount) and (2) the amount of spending above the MAP that is necessary to meet the 1 percent of total spending target for the outlier policy (referred to as the Fixed Dollar Loss (FDL) amount). The outlier threshold is the sum of the MAP and the FDL dollar amounts. Currently, a single year of ESRD PPS claims (from two calendar years prior to the payment year) is used to calculate the MAP and FDL amounts, which are inflated to account for price changes between the estimation year and the payment year. CMS uses a blended four-quarter moving average of the ESRD market basket price proxies for pharmaceuticals to inflate drug prices, a CPI forecast to inflate lab test prices, and a 0 percent inflation factor for supplies because those prices are predetermined.

¹³ Medicare Payment Advisory Commission. 2018. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2019. August 31. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.

¹⁴ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. Proposed Rule. *Federal Register* 87, no 123 (June 28): 38464–38586.

¹⁵ The remainder of the ESRD PPS bundle is made up of items and services that were included in the composite rate, used for dialysis payments prior to 2011. Items and services that were formerly separately billable are generally drugs, labs, and related services.

CMS funds the outlier policy by withholding 1 percent of total expected spending.¹⁶ If the outlier threshold is too high, less than 1 percent of total expected spending will be paid through the outlier policy and total ESRD PPS payments will be lower than intended (and vice versa if the outlier threshold is set too low). Since 2011 when the ESRD PPS was established, CMS has set the outlier threshold too high. Over the last three years, CMS has paid out between 0.4 percent and 0.6 percent of the outlier pool in each year. Consequently, to better target the 1.0 percent of total payments, CMS is proposing to change the method for projecting the FDL for adults.

For the CY 2023 ESRD PPS, CMS's proposal would:

- calculate the FDL amounts (using the agency's established method) that would have achieved the 1.0 percent outlier target (referred to as the "*retrospective*" FDL amounts) for the three most recent years with available data, relative to the rule year (for CY 2023, this would include data from CY 2019, CY 2020, and CY 2021). Retrospective FDL amounts would be derived from: (1) ESRD PPS claims from each of the three years, (2) the latest available prices of ESRD outlier services, and (3) the proposed base rate for the rule year.
- for years that immediately follow the end of a period during which an item or service was paid under the ESRD transitional add-on payment policies, CMS would adjust the calculation of the retrospective FDL amounts to account for differences in outlier-eligible services across the three most recent years with available data and the rule year.
- apply linear regression methods to calculate the historical trend in FDL amounts based on the retrospective FDL amounts from the three most recent years with available data. CMS would project this trend forward to determine the appropriate FDL amount for the rule year.

Under CMS's proposal, the CY 2023 FDL amounts for adults would be set at \$40.75. By comparison, the CY 2022 FDL amount for adults was \$75.39. CMS is not proposing to change the calculation of the average spending on separately billable services (i.e., the MAP amount) for CY 2023.

Comment

The Commission supports CMS's proposal to set the FDL amounts using a trend based on ESRD PPS claims data from the three most recent available data years. In our comment letter dated August 30, 2021, the Commission suggested that CMS use an approach that reflects the trend over time in spending for items in the ESRD bundle that were separately billable prior to 2011.¹⁷ CMS's proposed approach is a viable step to more accurately achieving the 1 percent outlier target. To provide a better sense of how effective the change in method is, CMS should consider reporting the CY 2023 values using CMS's current approach for comparison with the provided CY 2023 values of the FDL using CMS's proposed approach.

¹⁶ When implementing the ESRD PPS in CY 2011, CMS funded the outlier pool by reducing the per treatment base rate by 1 percent to account for the proportion of the estimated total payments that are outlier payments.

¹⁷ Medicare Payment Advisory Commission. 2021. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2022.

https://www.medpac.gov/wp-content/uploads/2021/10/08302021_ESRD_CY_2022_MedPAC_Comment_SEC.pdf.

Although the proposed method is likely to improve outlier payment accuracy, the Commission urges CMS to refine its approach for applying the pricing data that the agency uses to project FDL amounts, particularly for drugs. Currently, CMS uses a blended four-quarter moving average of the ESRD market basket price proxies for pharmaceuticals to inflate drug prices to the rule year. The average sales price (ASP) data that CMS uses to determine facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRD market basket pharmaceutical price proxies. During the most recent four-year period that data are available, our analysis shows that the ASPs of nearly all the commonly used erythropoietin stimulating agents (ESAs), iron products, and vitamin D analogs declined (Table 1). By contrast, the price indexes that CMS would use to measure the change in the prices of ESAs, iron agents, and all other drugs (including vitamin D analogs) increased by 20 percent, 3 percent, and 7 percent, respectively, between January 2018 and January 2022.

Table 1. ASP values of commonly used drugs under the ESRD PPS bundle has declined between 2018 and 2022

		2018 Q1	2022 Q1	
Functional category	Drug	Payment per unit		Aggregate change
Anemia management	Darbepoetin alfa	\$3.90	\$3.09	-21%
Anemia management	Epoetin alfa	\$1.21	\$0.82	-32%
Anemia management	Epoetin beta	\$1.63	\$1.51	-7%
Anemia management	Sodium Ferric Gluconate	\$2.16	\$1.92	-11%
Anemia management	Iron Sucrose	\$0.24	\$0.22	-7%
Bone and mineral metabolism	Paricalcitol	\$0.79	\$0.69	-12%
Bone and mineral metabolism	Doxercalciferol	\$0.44	\$0.39	-11%
Bone and mineral metabolism	Calcitriol	\$0.61	\$0.72	19%

Note: ASP (average sales price), ESRD (end-stage renal disease), PPS (prospective payment system), Q (quarter). Values represent ASP + 6 percent. The above drugs account for about 85 percent of utilization of drugs (as measured by applying 2021 ASP values to the number of units reported on dialysis claims) that were separately billable prior to 2011.

Source: CMS's ASP quarterly files and MedPAC analysis of the CMS's 2020 100 percent institutional outpatient file.

By using a trend of claims data for outlier-eligible services to project the FDL amount for the rule year, CMS's proposal reasonably captures changes in utilization and improves the likelihood that the 1 percent outlier target will be achieved. However, the method of inflating MAP and FDL amounts that CMS continues to use differs considerably from actual drug price trends based on ASP data. We think CMS needs to account for both utilization and price trends to prevent continued overestimates of MAP and FDL amounts and underpayments for outlier services. To achieve the 1 percent outlier target, CMS should apply the proposed method of calculating FDL amounts and use a drug price inflation factor based on ASP values.

Revising the definition of an ESRD oral-only drug

CMS is proposing to modify the definition of an oral-only drug to specify that *equivalence* refers to functional equivalence. CMS proposes to define an oral-only drug as a drug or biological product with no functional equivalent or other form of administration other than the oral form; this definition would be effective as of January 2025.

Comment

The Commission supports CMS's proposal to modify the definition of an oral-only drug to specify that equivalence refers to functional equivalence. We believe that this proposal would help maintain the integrity of the ESRD PPS bundle. The ESRD bundle defines the set of ESRD-related services that are commonly provided during dialysis treatment. The ESRD PPS establishes a single payment amount for services commonly provided during dialysis treatments and additional payments for cases in which home dialysis training is provided or certain costs are extremely high. In the Commission's view, an important goal of the ESRD PPS is to give ESRD facilities an incentive to provide ESRD-related items and services as efficiently as possible. We think this goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Including all items and services with a similar function in the bundle fosters competition for ESRD-related items and services and generates incentives for dialysis providers to constrain their costs.

Request for information on the payment for new ESRD drugs after the end of their TDAPA period

When CMS implemented the ESRD bundle in 2011, the agency argued for a broad interpretation of the items and services to be included in the bundle, and it established 11 functional categories for ESRD-related drugs included in the bundle. The functional categories were defined to include drugs that were, before 2011, formerly paid under the prior ESRD payment system's prospective payment—the composite rate—and ESRD-related drugs that were separately billable (e.g., ESAs, iron agents, and vitamin D agents).

In 2016, to comply with a Protecting Access to Medicare Act of 2014 mandate related to inclusion of new ESRD-related injectable and intravenous drugs in the PPS payment bundle, CMS implemented a policy that pays a TDAPA for:

- *New ESRD-related injectable drugs not in 1 of the 11 functional drug categories included in the PPS payment bundle*—Such drugs are eligible for a TDAPA for at least two years, until sufficient rate-setting data are available. When the TDAPA period ends, CMS includes the drug in the PPS payment bundle (by adding a new functional category or modifying an existing one) and adjusts the PPS base rate, if appropriate, to reflect changes to the functional categories. To date, no new ESRD-related injectable drug has qualified under this TDAPA policy.
- *ESRD-related oral-only drugs (calcimimetics and phosphate binders) once the Food and Drug Administration (FDA) approves a functionally 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 are included in the PPS payment bundle. To date, calcimimetics have been paid under this TDAPA policy (2018-2020) and since 2021, included in the PPS payment bundle (with an increase to the base payment to account for their use).

In its 2019 and 2020 ESRD PPS final rules, CMS expanded the TDAPA policy to allow add-on payments for all new ESRD injectable products (with the exception of certain drugs, including generics)¹⁸ that are in an existing ESRD-related functional category and approved by the FDA on or after January 1, 2020. In other words, the expanded TDAPA policy makes an add-on payment for any new and qualifying ESRD-related product for two years, even for a new drug with a functional equivalent already included in the PPS payment bundle. After two years, CMS includes the new drug in the PPS payment bundle but does not change the ESRD PPS base payment rate (because the functional categories are unchanged). According to CMS, the expanded TDAPA policy is intended “to promote innovation and bring more high-value drugs to market.”¹⁹ As of April 2022, the first product (Korsuva) has qualified for an add-on payment under the expanded TDAPA policy.

According to the proposed rule, since 2019, dialysis associations and pharmaceutical manufacturers have raised concerns about payment following the TDAPA period for new ESRD drugs that are in an existing ESRD functional category. Specifically, stakeholders assert the following:

“...unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics, then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when

¹⁸ The following drugs are excluded from TDAPA eligibility: generic drugs approved under section 5050(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7, or 8.

¹⁹ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program; end-stage renal disease prospective payment system, 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 (DMEPOS) Competitive Bidding Program (CBP) and fee schedule amounts, and technical amendments to correct existing regulations related to the CBP for certain DMEPOS. *Federal Register* 83, no. 139 (July 19): 34304.

the TDAPA period ends. Further ... uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA.”²⁰

Consequently, CMS is considering whether it would be appropriate to establish an add-on payment adjustment for certain ESRD drugs in existing ESRD functional categories after their TDAPA period ends. The agency’s possible approaches include establishing an add-on payment that would be based on the product’s cost alone or include an adjustment (i.e., offset) based on the cost per treatment of all other formerly separately billable ESRD drugs. CMS is specifically seeking feedback on:

- *Question 1:* Is an add-on payment adjustment for certain drugs in existing ESRD functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS use to determine which drugs get an add-on payment?
- *Question 2:* If an add-on payment is needed, which method is most appropriate?

Comment

The Commission’s comments focus on the first question—whether the ESRD PPS should include an add-on payment for certain ESRD drugs, and the criteria needed to determine which ESRD drugs would be included under such a policy.

Is an add-on payment adjustment for certain ESRD drugs in existing ESRD functional categories after their TDAPA period ends needed?

The Commission is strongly opposed to an add-on payment adjustment after the TDAPA period ends for any ESRD drug in one of the 11 ESRD functional categories

In the Commission’s view, an important goal of the ESRD PPS is to give nephrologists and ESRD facilities an incentive to provide ESRD-related items and services as efficiently as possible. This goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of the items and services provided to dialysis patients. Including all items and services with a similar function (i.e., functionally equivalent) in the bundle reduces incentives to overutilize drugs (to the extent clinically possible), fosters competition for ESRD-related items and services, and generates pressure on manufacturers to reduce prices. For example:

²⁰ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. *Federal Register* 87, no. 123 (June 28): 38464.

- The Commission’s analysis has shown that the use of ESRD drugs in the PPS bundle (including ESAs, which are used in anemia management) has declined in aggregate.²¹ According to CMS, while the ESRD PPS impacted use of certain ESRD services, the payment method has not resulted in sustained negative changes in beneficiaries’ outcomes.^{22, 23}
- Both MedPAC and CMS analysis of ESAs (which are included in the ESRD bundle) has shown that price competition increased and ESA costs decreased after the market entry of a new ESA in 2015.^{24, 25} The Commission has also found increased price competition among vitamin D agents (which are also included in the ESRD bundle).²⁶

When CMS first proposed expanding the TDAPA policy to allow add-on payments for all new ESRD injectable products that are in an existing ESRD-related functional category, the Commission raised concerns—specifically, that such an expansion would undermine the structure of the ESRD PPS (by unbundling services) and would encourage high launch prices of new drugs and other technologies.^{27, 28} We also noted that payments under the TDAPA for new dialysis drugs in an existing functional category are duplicative of the payment that is already made as part of the ESRD bundle. The cost of providing all drugs in a given functional category is included in the base rate; Medicare pays ESRD facilities twice for a drug that is included in an existing functional category and that is paid separately under the TDAPA. Consequently, in our June 2020 report to

²¹ Medicare Payment Advisory Commission. 2022. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC. We estimated ESRD drug use by holding price constant and multiply drug units reported on ESRD facility claims in a given year by 2021 average sales price + 0 percent. Between 2010 (the year prior to the ESRD PPS) and 2020 (the most current year data are available), ESRD drug use per treatment declined in aggregate by nearly 60 percent.

²² Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. *ESRD prospective payment system claims-based monitoring program*. Baltimore, MD: CMS.

²³ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. Proposed Rule. *Federal Register* 88, no. 123 (June 28): 38464.

²⁴ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

²⁵ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, and End-Stage Renal Disease Quality Incentive Program. *Federal Register* 82, no. 127 (July 5): 31199.

²⁶ Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC.

²⁷ Medicare Payment Advisory Commission. 2019. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2020. September 20. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09202019_esrd_cy2020_medpac_comment_v2_sec.pdf.

²⁸ Medicare Payment Advisory Commission. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2019. August 31. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.

the Congress, we recommended the elimination of the expanded TDAPA policy for new ESRD drugs in an existing ESRD functional category.²⁹ Eliminating the TDAPA for these drugs would maintain the integrity of the ESRD PPS bundle and create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs.

The Commission raised similar concerns about undermining the integrity of the bundle and limiting the competitive forces that generate price reductions in response to CMS's proposal that pays a transitional add-on payment for new and innovative non-capital-related ESRD equipment and supplies (TPNIES) beginning in CY 2020 and its proposal that expanded the TPNIES to include capital-related assets that are home dialysis machines when they are used in a patient's home beginning in CY 2021.

Some stakeholders have asserted that it is not appropriate to assume that the base rate is sufficient to support new drugs that represent a clinical improvement. However, in the Commission's view, the competitive forces within the PPS payment bundle are undermined by paying a TDAPA for new drugs in an existing ESRD functional category or paying an add-on payment for these ESRD drugs after their TDAPA period ends. Both policies fail to create pressure on drug manufacturers to constrain prices for new and existing ESRD drugs and fail to maximize the incentive for nephrologists and ESRD facilities to provide ESRD-related items and services as efficiently as possible. Bundled payment encourages thoughtful consideration of the items and services provided to patients. Including all ESRD drugs in an existing functional category (and thus with a similar function) in the bundle fosters competition for these products and generates pressure to constrain prices.

The Commission recognizes that as new products are added to the bundle and diffused into medical practice, there may be a need for rebasing to keep Medicare payments aligned with providers' costs. For example, the Congress mandated that the Secretary rebase the ESRD PPS base payment rate in 2014 to account for the decline in the use of ESRD drugs covered under the bundle. The Commission's annual payment adequacy analysis can help inform policymakers about the alignment of Medicare's payments to providers' costs. Our payment adequacy analysis also tracks dialysis drug use and changes in patients' outcomes over time.

What criteria should CMS use to determine which products would be included in the calculation for an add-on payment adjustment after the end of the TDAPA period?

We reiterate that CMS should not establish an add-on payment adjustment for any ESRD drugs in existing ESRD functional categories after their TDAPA period ends. However, if CMS decides to implement such a policy, then the agency should limit such an adjustment to products that represent a substantial clinical improvement compared with products in the bundle. In the 2018, 2019, and 2020 rule-making processes, we asserted that if the agency adopts a transitional add-on payment for drugs or equipment and supplies:

- CMS should require that the new product be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment

²⁹ Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

bundle. The agency included such a criterion for substantial clinical improvement when it implemented the TPNIES in 2020.

- CMS should not use FDA’s approval processes as a proxy for or in place of a substantial clinical improvement criteria to determine eligibility. Participation in FDA’s approval pathways on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. The Commission also believes that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population. The Commission recognizes the unique roles across federal agencies with respect to approving new technologies for marketing in the U.S. and increasing payment for Medicare beneficiaries. The evaluation of the evidence of whether a new technology improves Medicare beneficiaries’ outcomes should rest with CMS.
- CMS should not make duplicative payments for a new product by paying both an add-on payment and paying for related services under the ESRD PPS base rate. That is, the agency should reduce any add-on amount to reflect the amount for similar items and services already included in the base rate. We applauded the agency for including an offset in the add-on payment policy when implementing the TPNIES for capital-related assets such as home dialysis machines when used in patients’ homes (i.e., a reduction to the TPNIES amount to reflect the amount already included in the base rate). We reiterate that CMS should adopt such an offset in the TDAPA policy for new ESRD drugs in an existing functional category or for non-capital-related assets paid under the TPNIES.
- CMS could consider paying a reduced percentage of the estimated incremental cost of a new item or service as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. CMS uses such an approach in setting the add-on payment for the TPNIES.

There are many design elements of an add-on payment adjustment on which CMS is not seeking comments, including the length of time for which the agency would pay an add-on payment adjustment for ESRD drugs in existing ESRD functional categories after their TDAPA period ends and whether such an add-on payment would be updated over time. Depending on the design of the add-on payment (i.e., whether the agency would update it on an annual basis), paying such an adjustment indefinitely could severely curtail any incentive for manufacturers to constrain the growth of drug prices.

Request for information on overarching principles for measuring health care quality disparities across CMS quality programs

CMS is working to advance health equity by designing and implementing policies and programs that support health for all beneficiaries. Accounting for health care disparities in quality measures is a cornerstone of their approach to advancing health care equity. CMS has proposed quality measure stratification (measuring performance differences among subgroups of beneficiaries) as a tool to address health care disparities and advance health equity. In this proposed rule, CMS is requesting information on principles and approaches that could be used in the ESRD Quality Incentive Program.

Comment

The Commission supports CMS’s overall efforts to measure and report health care disparities by stratifying quality measure results for different subgroups of beneficiaries. We recognize that optimal health outcomes can be adversely affected by social risk factors. The Commission has traditionally focused on modifying payment systems to incentivize health care providers and payers (e.g., Medicare Advantage plans) to deliver high-quality care in the most efficient manner. While strong incentives for achieving value-based care objectives are critical, it is also important to apply such incentives fairly—that is, to recognize when these incentives can undermine access to care for beneficiaries. The Commission’s recent work to account for differences in patients’ social risk factors in quality payment programs and revisit payment for safety-net providers aims to improve incentives to deliver high-quality and efficient care. In the past we have highlighted some disparities in care when we have identified them in our payment adequacy analyses. Moving forward, the Commission plans to more deliberately incorporate analysis by social risk factors, in particular income and race/ethnicity, into our payment adequacy and other analyses. Our comment letter on the inpatient hospital proposed rule offers a complete discussion about MedPAC’s comments on the agency’s efforts to establish overarching principles for measuring equity and health care quality disparities across CMS quality programs.³⁰

Conclusion

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission values the ongoing collaboration between CMS and MedPAC staff on technical policy issues, and we look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC’s Executive Director, at (202) 220-3700.

Sincerely,



Michael E. Chernew, Ph.D.
Chair

³⁰ Medicare Payment Advisory Commission. 2022. MedPAC comment letter regarding hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system. June 16. https://www.medpac.gov/wp-content/uploads/2022/06/06162022_FY2023_IPPS_LTCH_MedPAC_COMMENT_v2_SEC.pdf