MEDPAC | Medicare Payment Advisory Commission

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Centers for Medicare & Medicaid Services
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P.O. Box 8010
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Attention: CMS-1830-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; 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* 90, no. 125, pp. 29342–29391 (July 2, 2025). 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:

- update the end-stage renal disease (ESRD) prospective payment system (PPS) base payment rate for calendar year (CY) 2026; and
- include a non-contiguous area payment adjustment (NAPA).

We also reiterate our prior comments about: (1) paying for phosphate binders under the ESRD PPS and (2) paying for certain new ESRD drugs in an existing ESRD functional category under a transitional drug add-on payment policy.

Update to the ESRD PPS base payment rate for CY 2026

Per statutory requirements, CMS proposes to update the ESRD PPS base rate for CY 2026 by 1.9 percent. This update is based on the ESRD bundled market basket (ESRDB) increase factor (of 2.7 percent) reduced by a multifactor productivity adjustment (of 0.8 percent). The proposed CY 2026 ESRD PPS base rate is $281.06, which is an increase of $7.24 to the current base rate of $273.82.[1]

[1] The update to the ESRD PPS base rate also reflects a proposed non-contiguous area payment adjustment (NAPA) budget-neutrality adjustment factor.

Comment

We support this proposal. In our March 2025 report to the Congress, the Commission's analysis of indicators of payment adequacy for the sector suggests that Medicare's payments to freestanding ESRD facilities in 2023 were adequate. Based on this assessment, the Commission recommended that, for 2026, the Congress should update the CY 2025 ESRD PPS base rate by the amount determined under current law.

Include a non-contiguous area payment adjustment

The base payment for each dialysis treatment is intended to cover all operating and capital costs that efficient providers incur in furnishing dialysis treatment episodes in dialysis facilities or in patients' homes. The base rate is adjusted for differences in labor costs by multiplying the labor-related portion of the base payment amount (55.2 percent) by an ESRD-specific wage index. CMS proposes to establish a new, budget-neutral facility-level payment adjustment that would be applied to the non-labor share of the ESRD PPS base rate (44.8 percent) for all ESRD PPS claims submitted by ESRD facilities in Alaska, Hawaii, and the Pacific Territories (or, Guam, American Samoa, and the Northern Mariana Islands), including treatments furnished at home and to pediatric ESRD beneficiaries.

CMS explains that the proposed non-contiguous area payment adjustment, or NAPA, is meant to account for higher non-labor costs for ESRD facilities in certain remote non-contiguous geographic areas relative to the contiguous U.S. According to CMS, this proposal responds to comments from interested parties during last year's ESRD PPS rulemaking process that asked the agency to consider factors that are unique to small island economies such as air freight shipping, greater utility costs, difficulty recruiting and retaining qualified health care professionals, and lack of economies of scale when compared to larger ESRD facilities located in the contiguous U.S.

CMS derived the upward payment adjustment factors (a 25 percent increase for facilities in Alaska and the Pacific Territories and a 21 percent increase for facilities in Hawaii) from a facility-level logarithmic regression that compared non-labor costs[2] in non-contiguous areas versus the contiguous U.S.[3,4] To achieve budget neutrality, CMS proposes to cap the adjustment factors at 25 percent,[5] and apply a budget-neutrality

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[2] CMS included the following "non-labor costs associated with furnishing renal dialysis services" from ESRD cost reports covering January 1, 2020, through December 31, 2022: non-salary costs associated with capital, administration, drugs, supplies, and laboratory tests.
[3] The treatment variables were indicators for four areas/groups of territories: (1) Alaska; (2) Hawaii; (3) Guam, American Samoa, and the Northern Mariana Islands; and (4) Puerto Rico and the U.S. Virgin Islands. The regression model specification included the following facility-level covariates: log quadratic facility treatment volume, rurality, wage index value, ownership type, percent of treatments which are Medicare treatments, percent of treatments which are home dialysis treatments, average case-mix adjustment multiplier for Medicare treatments, and indicators for cost report year.
[4] CMS's regression model did not indicate that non-labor costs are higher in Puerto Rico and the U.S. Virgin Islands relative to the contiguous U.S.
[5] Without such a cap, the NAPA factors would be higher than 25 percent for facilities in Alaska, Guam, American Samoa, and the Northern Mariana Islands.

factor of 0.99859 to the CY 2026 ESRD PPS base rate. This would, in turn, reduce the ESRD PPS base rate by 0.1 percent, or $0.35, for the 7,522 ESRD facilities in the contiguous U.S.[6]

Comment

The Commission recognizes the importance of aligning Medicare's payments with facility costs to promote beneficiary access to care and payment accuracy. However, the Commission does not support CMS's proposed new payment adjustment because the policy does not accurately target facilities that are both critical to beneficiary access and have high costs warranting a payment adjustment. In the proposed rule, CMS does not analyze indicators of beneficiary access, such as the capacity of providers to meet beneficiary demand and changes in the volume of services, in the selected non-contiguous U.S. areas. Moreover, an area-level payment adjustment does not target payments in the way that facility-level adjustments do. We reiterate our comment on the CY 2025 proposed rule and our recommendation from our 2020 report to the Congress: an adjustment that serves to preserve access to dialysis should focus on isolated and low-volume facilities.[7,8]

Our analyses have repeatedly shown a relationship between ESRD facility volume and costs: ESRD facilities with greater service volume (as measured by total treatments) tend to have lower costs per treatment.[9,10] We note that this relationship occurs at the level of the facility, not at the service area. The Commission's analysis of Addendum B of the proposed rule finds that about 59 percent of ESRD facilities in Alaska, Hawaii, and the Pacific Territories have a total number of hemodialysis-equivalent treatments exceeding 10,000 treatments per year (which is also the mean number of treatments in CY 2023),[11] compared with 39 percent in facilities in the contiguous U.S.[12] The majority of facilities in these non-contiguous areas, therefore, have above-average service volumes. Furthermore, the number of dialysis facilities and dialysis treatment stations in these non-contiguous areas have been generally steady in recent years, indicating that beneficiary access to care remains positive.[13] Therefore, CMS's proposed increased payments do not appear to be necessary to maintain access to care in these areas, and thus would be poorly targeted.

We agree with CMS that "there is inherent uncertainty in the result of the regression analysis" given the small number of ESRD facilities included in the regression analysis,

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[6] Addendum B of the CY 2026 ESRD PPS proposed rule identifies 7,582 total facilities, among which 7,523 would have a NAPA multiplier of 1.0, 41 would have a NAPA multiplier of 1.21, and 18 would have a NAPA multiplier of 1.25.
[7] Medicare Payment Advisory Commission, 2020. *Medicare and the health care delivery system*. Washington, DC: MedPAC.
[8] Medicare Payment Advisory Commission. 2024. MedPAC 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.
[9] Medicare Payment Advisory Commission, 2020. *Medicare and the health care delivery system*. Washington, DC: MedPAC.
[10] Medicare Payment Advisory Commission, 2025. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[11] The Commission derived the mean number of treatments via the CY 2023 cost reports from freestanding ESRD facilities.
[12] These treatment counts represent total number of hemodialysis-equivalent treatments, including treatments for non-Medicare patients.
[13] According to online data from CMS's S&C's Quality, Certification and Oversight Reports, the total number of ESRD facilities in the following non-contiguous areas are: 9 in 2020 and 2024 in Alaska; 2 in 2020 and 2024 in American Samoa; 6 in 2020 versus 5 in 2024 in Guam; 34 in 2020 versus 42 in 2024 in Hawaii; and 2 in 2020 versus 3 in 2024 in the Northern Mariana Islands. The total number of dialysis treatment stations are: 158 in 2020 and 2024 in Alaska; 42 in 2020 and 2024 in American Samoa; 107 in 2020 versus 90 in 2024 in Guam; 880 in 2020 versus 936 in 2024 in Hawaii; and 29 in 2020 versus 19 in 2024 in the Northern Mariana Islands.

particularly in the treatment groups.[14] The Commission is also concerned that, by grouping all ESRD facilities in the contiguous U.S. into a single reference group, CMS's regression analysis does not take into account the variation in costs between facilities within the contiguous U.S. As a result, under this proposal, not only would low-volume, isolated ESRD facilities in the contiguous U.S. be exempted from a new payment adjustment, their base rate would be further reduced as a result of the NAPA budget-neutrality factor.

The Commission reiterates that CMS should replace the current ESRD PPS low-volume payment and rural payment adjustments in the ESRD PPS with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.[15] Such an approach would target additional resources to facilities that are critical for beneficiary access, both in the contiguous U.S. and in non-contiguous areas. However, if CMS decides to pursue adding a new payment adjustment to address "certain unrecognized costs which are not accounted for by any of the existing payment adjustments under the ESRD PPS,"[16] the agency should:

- target the payment adjustment to be facility specific, and not applied statewide;
- target facilities that are low volume and isolated; and
- consider all facilities in the U.S. for the potential payment adjustment, not just facilities in Alaska, Hawaii, and the Pacific Territories.

Paying for oral-only phosphate binders under the ESRD PPS

Per regulatory and statutory requirements, in CY 2025, CMS finalized its method for incorporating oral-only phosphate binders into the Part B ESRD PPS bundle. Specifically, CMS began paying for oral-only phosphate binders using a transitional drug add-on payment adjustment (TDAPA) as of January 1, 2025, at 100 percent of the drug's average sales price (ASP) plus a $36.41 flat rate increase to the monthly TDAPA amount for claims which utilize phosphate binders. According to CMS, the monthly flat rate increase accounts for the incremental operational costs, such as distribution fees, mailing fees, storage fees, and increased labor costs, incurred by ESRD facilities for the provision of phosphate binders.[17]

CMS proposes to continue paying for oral-only phosphate binders under a TDAPA policy at 100 percent of ASP plus the monthly flat rate increase—$36.41 per month—in CY 2026.

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[14] The regression model compares the non-labor costs in the following non-contiguous areas relative to non-labor costs across all facilities in the contiguous U.S.: 9 facilities in Alaska; 41 facilities in Hawaii; 11 facilities in Guam, the Northern Mariana Islands, and American Samoa; and 54 facilities in Puerto Rico and the U.S. Virgin Islands.
[15] Medicare Payment Advisory Commission, 2020. *Medicare and the health care delivery system*. Washington, DC: MedPAC.
[16] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2025. 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* 90, no. 125 (July 2): 29342–29391.
[17] CY 2025 ESRD PPS final rule. https://www.govinfo.gov/content/pkg/FR-2024-11-12/pdf/2024-25486.pdf.

Comment

While we support paying for oral-only dialysis drugs under the ESRD PPS at each drug's ASP plus 0 percent, we do not support the method that CMS uses to determine the additional monthly fixed amount, a payment adjustment that is included for every monthly ESRD PPS claim that includes phosphate binders. CMS derived the flat rate increase to the add-on payment amount for phosphate binders from 6 percent of the weighted average of Medicare expenditures for phosphate binders per month under Part D. That is, CMS calculated the fixed payment amount at an amount that the agency believed best approximates 6 percent of ASP.[18] As we noted in our comment letter on the CY 2025 proposed rule, the Commission does not support linking the monthly flat rate increase to a drug's ingredient cost (ASP for ESRD drugs paid under the add-on payment amount). The monthly flat rate increase for phosphate binders is intended to cover reasonable costs that are directly related to providing the drug. There is no consensus on the original intent of the percentage add-on to ASP.[19]

We reiterate that if CMS elects to include a monthly flat rate in the TDAPA for phosphate binders, the agency should examine the dispensing fees for phosphate binders paid under Part D to assess if such data are appropriate to use under the ESRD PPS.[20] As we said in our 2024 comment letter to the Secretary, the median Part D dispensing fee was $0.50 per claim in 2021 for the six common types of phosphate binders furnished to beneficiaries on dialysis. The Commission has also found that under Part D, dispensing fees for generic drugs are typically a fixed dollar amount (i.e., not always related to the price of the product), and that similar to dispensing fees paid in the commercial sector, Part D plans typically pay dispensing fees of $1 per claim or less.

Paying for certain new ESRD drugs under a transitional drug add-on payment adjustment policy

In its 2019 and 2020 ESRD PPS final rules, CMS adopted a TDAPA policy to allow, in a non-budget-neutral manner, add-on payments for all new ESRD injectable products (with the exception of certain drugs, including generics) that are in an existing ESRD-related functional category and approved by the FDA on or after January 1, 2020. In other words, this TDAPA policy makes an add-on payment for any new and qualifying ESRD product for two years, even for a new drug with a functional equivalent already included in the PPS payment bundle. In the 2024 ESRD PPS final rule, CMS adopted a post-TDAPA policy that pays, in a non-budget-neutral manner, add-on payments for a three-year period at the end of the TDAPA's two-year period.

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[18] CY 2025 ESRD PPS final rule. https://www.govinfo.gov/content/pkg/FR-2024-11-12/pdf/2024-25486.pdf.
[19] Medicare Payment Advisory Commission. 2024. MedPAC comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2025. https://www.medpac.gov/wp-content/uploads/2024/08/0822024_MedPAC_ESRD_PPS_CY2025_comment_v3_SEC.pdf.
[20] Medicare Payment Advisory Commission. 2024. MedPAC comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2025. https://www.medpac.gov/wp-content/uploads/2024/08/0822024_MedPAC_ESRD_PPS_CY2025_comment_v3_SEC.pdf.

Comment

In our June 2020 report to the Congress, we recommended the elimination of the TDAPA policy for new ESRD drugs in an existing ESRD functional category.[21] 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.

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.

As we said in our 2022 ESRD PPS comment letter to the Secretary, if CMS continues to pay an add-on adjustment for new ESRD drugs in an existing ESRD functional category, the agency should:[22]

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

- 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. CMS included an offset in the add-on payment policy (transitional add-on payment for new and innovative equipment and supplies (TPNIES)) when implementing the add-on payment for capital-related assets such as home dialysis machines when used in patients' homes.

- 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.

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[21] Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[22] Medicare Payment Advisory Commission. 2022. MedPAC comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2023. August 19. https://www.medpac.gov/wp-content/uploads/2022/08/08192022_ESRD_CY2023_MedPAC_COMMENT_SEC.pdf

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,

Michael E. Chernew, Ph.D.
Chair