



September 4, 2020

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1732-P
P.O. Box 8010
Baltimore, MD 21244-8013

RE: CMS–1732–P: 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

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing to provide comments on the 2021 ESRD PPS/QIP Proposed Rule. Our comments address the following issues:

- **Appropriate Date Interval for Calculating the ESRD PPS Base Rate for Calcimimetics**
- **Use of TDAPA and TPNIES to Promote Innovation**

Appropriate Date Interval for Calculating the ESRD PPS Base Rate Addition for Calcimimetics

In the proposed rule, CMS not only solicits comments on the proposed use of calendar years (CYs) 2018 and 2019 claims data to determine the utilization of calcimimetics for purposes of calculating the proposed addition to the ESRD PPS base rate to account for calcimimetics, but also solicits comments as to whether the Agency should instead use a single year (CY 2018 or CY 2019) rather than both CYs 2018 and 2019 in its methodology. RPA commends CMS for its foresight in raising this question.

RPA shares the concerns of other groups in the kidney care community that the CY 2018 data does not offer an accurate representation of the actual use of calcimimetics. Given that CMS only began paying for calcimimetics under the ESRD PPS using the transitional drug add-on

payment adjustment (TDAPA) on January 1, 2018, utilization data for 2018 will be distorted by the incremental adoption of these products by some providers and facilities, as well as the development, implementation, and evolution of protocols for their use occurring during 2018.

Further, we are aware that in other Medicare payment programs such as the hospital inpatient and outpatient prospective payment systems, typically the most recent 12 months of data is used to implement policies of this nature. Whether that means in this case using the most recent 12 months of data within a single calendar year (which would indicate the use of CY 2019 data), or whether it could be spread over two calendar years (such as beginning with the second quarter of 2019 and extending through March 31, 2020) is a determination for CMS to make. However, in either case RPA believes that the use of CY 2018 utilization data that is likely not optimally representative of calcimimetics use should not be included in base rate calculations for the add-on.

RPA urges CMS to not include CY 2018 utilization data in calculating the addition to the PPS base rate for calcimimetics.

Use of TDAPA and TPNIES to Promote Innovation

RPA believes that one of the most positive advances in the ESRD PPS policy methodology in recent years is the development and use of mechanisms such as the transitional drug add-on payment adjustment (TDAPA) and the transitional add-on payment for new and innovative equipment and supplies (TPNIES) as ways to promote innovations in care for Medicare beneficiaries with ESRD. As the Administration, CMS, and any other observer of ESRD care delivery is aware, innovation has been sorely lacking in kidney care over the past few decades, and has substantially lagged behind the progress made in other disease states over that time. TDAPA and TPNIES are meaningful efforts to address that shortfall, and CMS is to be commended for seeking to address it.

That said, RPA believes that there are steps that could be taken to more fully realize the potential of TDAPA and TPNIES. While the simple existence of TDAPA and TPNIES represent progress, we concur with Kidney Care Partners (KCP) that they do not address the longitudinal implementation of the innovations they are intended to promote.

Steps to address these concerns would include:

- **To implement payment add-ons created by both TDAPA and TPNIES for a three-year interval as a standard rather than the current two-year period;**
- **To seek ways to upwardly adjust the ESRD PPS base rate when an innovative drug, item of equipment, or supply is identified that truly improves patient care, without requiring corresponding budget neutrality; and**
- **To provide flexibility in evaluating new drugs and products such that the bar to clear in introducing a new therapeutic innovation into the bundle is not so high as to deter research and development advancements (as has been the case for far too long), while still accounting for the need to demonstrate clinically significant**

improvement. Special consideration should be given to study children as well as adults to ensure appropriate innovation for pediatric kidney care.

RPA believes that making these changes in a fiducially responsible way would facilitate CMS' ability to take advantage of the opportunities for advancement occurring in medical innovation while soundly investing in improvements in the future of kidney patient care.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work on the ESRD Prospective Payment System. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in black ink, reading "Jeffrey A. Perlmutter" followed by a stylized flourish.

Jeffrey A. Perlmutter, MD
President