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August 23, 2024

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Centers for Medicare & Medicaid Services
CMS-1805-P
P.O. Box 8010
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1805-P: 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

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 2024 ESRD PPS/QIP Proposed Rule. Our comments address the following issues:

- Innovation Payment and Inclusion of Phosphate Lowering Therapies in the PPS Bundle
- Coverage of Acute Kidney Injury Dialysis in the Home Setting
- Home Dialysis Training Payment Revisions and Budget Neutrality
- Conditions for Coverage Revisions
- Clinician-Level Fee Schedule Barriers to Home Dialysis Adoption

Innovation Payment and Inclusion of Phosphate Lowering Therapies in the PPS Bundle

As referenced in previous RPA comments on the Prospective Payment System (PPS), the existence of the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and the Transitional Drug Add-On Payment Adjustment (TDAPA) demonstrates that CMS recognizes the need for innovative therapies in dialysis care, the importance of which is signified by appropriate and equitable reimbursement for these care advancements. Other Medicare payment systems employ processes like pass-through payments and new CPT code development pathways to pay for innovation in those schemas, and even during this comment period CMS issued a final notice for the new Transitional Coverage for Emerging Technologies (TCET) pathway for certain FDA designated breakthrough devices. However, the ESRD PPS remains the only payment system without a process for providing stable and ongoing payment updates for care innovations. The end result of this circumstance is that dialysis patients - among the most vulnerable and chronically ill patients in the U.S. - are denied access to innovative treatment options in a way that affects no other sub-population of Medicare beneficiaries.

Further, included in the 2024 Medicare Physician Fee Schedule proposed rule was a table outlining Beneficiary Service Utilization by Payment Impact Specialty Across Demographic and Equity Characteristics, which showed that that nephrology as a specialty treats the highest percentages of African American, Hispanic, and Indigenous patients of all Medicare reporting physician specialties. Nephrologists also treat the highest percentage of low-income subsidy (LIS) patients. Thus, using CMS' own data as a proxy for dialysis care, any PPS policy decision CMS makes has lasting implications for marginalized and minoritized patient populations. RPA recognizes that CMS has made considerable progress on health equity issues, and we acknowledge the legislative restraints associated with the PPS. However, we also believe that CMS has the administrative prerogative to make determinations regarding innovation that would promote novel therapies in care provided to largely vulnerable patients but has not done so. The absence of an innovation adjuster in the PPS clearly has health equity implications for dialysis patients.

An example of such a decision was the Agency's choice to include the new phosphate lowering agent tenapanor in the ESRD PPS bundle as of January 1, 2025. This therapy, which obtained FDA marketing approval in the fourth quarter of 2023, is in our estimation truly novel and represents breakthrough scientific advancement in phosphate management. As such, RPA along with many members of the community support legislation to exclude tenapanor from the bundle for two years as such an exclusion would promote patient access to care and physician prescribing autonomy. However, if the Agency had made what we believe would have been a forward thinking and innovation-centric determination to exclude tenapanor from the PPS

bundle, Congressional action would not be necessary. RPA would therefore urge CMS in the future to identify instances where decision can be made to promote innovation, patient access to care, and health equity.

Coverage of Acute Kidney Injury Dialysis in the Home Setting

In the rule, CMS proposes to provide Medicare payment for the treatment of patients with acute kidney injury (AKI) in the home setting. RPA fully supports this proposal. As CMS cites from our comments on the 2017 ESRD PPS rule, RPA “has long supported access to all dialysis modalities for beneficiaries with AKI as it aligns with the goals to expand access to home dialysis and increase the number of programs utilizing emergent or urgent [peritoneal dialysis] PD, as opposed to [hemodialysis] HD, as rescue therapy for patients presenting in urgent need.”

Further, we concur with the arguments in favor of coverage for AKI care for home patients cited the lessons learned from the pandemic regarding the rapid deployment of PD at home for AKI patients, and that AKI patients dialyzing at home who transition to ESRD may be more likely to remain as home dialysis patients, helping to achieve one of CMS’ long-standing objectives in dialysis care.

Home Dialysis Training Payment Revisions and Budget Neutrality

CMS proposes to allow home dialysis training to be provided to home AKI patients, and this is of course an appropriate decision that should positively contribute to the home AKI patient’s dialysis journey. However, the Agency proposes to apply a budget neutrality adjustment to the home training payment and includes in the rule utilization estimates upon which the budget neutrality adjustment is based.

First, RPA would urge CMS to at minimum delay the proposal to apply the budget neutrality adjustment to the home dialysis training payment until at least January 1, 2027, as we believe it is unnecessary and premature at this juncture. With all due respect, the Agency does not have a great history of developing accurate utilization estimates in the dialysis payment arena, nor in correcting previous inaccurate estimates in subsequent rulemaking. A two-year delay would provide CMS with at least 12-18 months worth of actual claims experience upon which to base the budget neutrality adjustment if it is necessary at that time. RPA is encouraged that CMS is seeking comments regarding the need for a home and self-dialysis training add-on payment adjustment for AKI beneficiaries, and our recommendation is that the Agency delay such an adjustment for at least two years.

Conditions for Coverage Revisions

RPA supports the clarifying revisions in the ESRD Conditions for Coverage (CfCs) to align with the changes in the rule to cover home dialysis services provided to AKI patients. We believe this is a

straightforward and common-sense modification that will benefit home AKI patients by ensuring that accountability for their care will be exercised through existing oversight structures such as the Quality Incentive Program (QIP), the ESRD Network and Network organizations, and the Conditions themselves.

Clinician-Level Fee Schedule Barriers to Home Dialysis Adoption

Included in the rule are a series of questions that CMS poses in an effort to improve its understanding of other policy interventions that may increase access to high quality home dialysis within the context of Innovation Center models and across CMS. Among these questions was:

How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?

RPA believes that two policy levers under CMS' administrative responsibilities that could be used to eliminate barriers to home dialysis are the kidney disease education (KDE) benefit and the home dialysis training CPT codes (90989 and 90993).

We posit that by any measure the KDE benefit has been woefully underutilized since its effective date of January 1, 2010. While more robust use of the services would benefit all potential dialysis patients, it would be especially useful in promoting the use of home modalities. At least part of the reason for this would be the stagnant valuation of the service codes assigned to the services, G0420 for the individual KDE sessions and G0421 for the group sessions. In fact, G0420 has actually decreased in valuation since 2011 (from 3.25 total RVUs in 2011 to 3.24 total RVUs proposed for 2025; comparatively G0421 has increased since 2011 from 0.77 to 0.78 for 2025). RPA recognizes that value for CPT and other services codes fluctuate for many reasons, and that it is also common for service code valuations to remain stable for a number of years. However, two factors that make this situation unique: (1) since these are G-codes, our understanding is that it is completely within CMS' prerogative to increase the values for these codes; and (2) given the Agency's pronounced emphasis in recent years on increasing home dialysis use, increasing the values for these services would seem to be a practical step that would increase utilization of these services.

Similarly, the home dialysis training service codes , CPT codes 90989 (for a completed course of home dialysis training) and 90993 (for a single training session when the course is not completed) have not been updated since their creation over three decades ago. These are unique service codes in that they do not have relative value units (RVUs) assigned to them but rather flat rates of \$500 for 90989 and \$20 per session for 90993 (this is the reason these codes do not appear in the actual Medicare fee schedule, since they are not RVU-based). As CMS

created the codes and set their values, RPA believes it is within the Agency's power to increase those values, and that this is a change that would directly affect home dialysis utilization positively. One final note regarding the home dialysis training service codes: because they don't show up in the fee schedule, some Medicare Administrative Contractors (MACs) have interpreted this to mean they are not covered services, despite this being explicitly stated in the Medicare claims manual. RPA would recommend that CMS at a minimum issue a transmittal clarifying that home dialysis training via CPT codes 90989 and 90993 are covered services in the Medicare physician fee schedule.

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, appearing to read "KBellovich", with a stylized flourish at the end.

Keith A. Bellovich, DO

President