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October 5, 2020

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

U.S. Department of Health and Human Services

ATTN: CMS-1734-P

P.O. Box 8016

Baltimore, MD 21244-8016

Re: CMS-1734-P; Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Proposed Rule

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. Part of RPA's mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA is writing to offer our input on the 2021 Medicare Fee Schedule Proposed Rule and Updates to the Quality Payment Program. RPA's comments address the following issues:

- **Revaluing Services that are Analogous to Office Visit/Outpatient E&M Visits; ESRD MCP Services**
- **Ongoing Reduction of Relativity Between Inpatient Dialysis Services and Associated Evaluation and Management Services**
- **Proposed 2021 Conversion Factor and Budget Neutrality**
- **Inclusion of Single Visit MCP Codes on Approved Telehealth List**
- **Coverage and Pricing for Percutaneous Creation of an Arteriovenous Fistula**
- **Proposed Removal of NCD #110.14 for Apheresis**
- **Refinements to the QPP for 2021**

1700 Rockville Pike • Suite 220 • Rockville, MD 20852

Phone: 301/468-3515 • Fax: 301/468-3511 • email: rpa@renalmd.org • www.renalmd.org

Annual Meeting • March 18-21, 2021 • New Orleans, LA

Revaluing Services that are Analogous to Office Visit/Outpatient E&M Visits: ESRD MCP Services

In the proposed rule for the 2020 physician fee schedule, CMS solicited comment on whether it would be necessary or beneficial to make systematic adjustments to services in the fee schedule closely tied to evaluation and management (E&M) services in order to maintain relativity between these services and office/outpatient E&M visits. RPA's response to that solicitation included a detailed history of the ESRD monthly capitated payment (MCP), listed the instances where the underlying E&M codes had been increased in value without those corresponding increases being applied to the MCP code family, and urged CMS to make proportional upward adjustments to the MCP codes accordingly.

The 2021 fee schedule rule proposes to make these changes, and RPA strongly supports this decision. We concur with the Agency that in improving payment accuracy for the ESRD MCP codes, it is supporting broader efforts to advance kidney health in the U.S.

RPA does share the concern of the American Society of Pediatric Nephrology (ASPN) regarding CPT code 90954 (the monthly dialysis code for patients age 2-11 years old, 4 or more visits), which the Agency did not propose to increase based on its valuation via a crosswalk to CPT code 99471 (Initial pediatric critical care, patients age 29 days-2 years) rather than using outpatient E&M services as building blocks. Further, we concur with ASPN that not revaluing CPT code 90954 will result in a rank order anomaly within the code family, so **RPA urges CMS to increase the RVUs for 90954 proportionate to the rest of the code family.**

RPA is also cognizant that there is a discrepancy in the proposed rule between the RVUs for CPT code 90966 (adult home dialysis) outlined in Table 19 of the text of the rule and those set forth in Addendum B. RPA supports finalization of the values that are proposed in Addendum B. We believe those values are reflective of the variance in physician work times noted in Table 20, as well as the need to maintain relativity in the code family and to eliminate any unnecessary adjudication of potential anomalies in the ESRD MCP code family.

RPA urges CMS to finalize the revised RVUs for the ESRD MCP code family as proposed in Addendum B of the 2021 fee schedule rule, with the exception of CPT code 90954, which should be increased proportionate to the rest of the code family.

Ongoing Reduction of Relativity Between Inpatient Dialysis Services and Associated Evaluation and Management Services

Similar to the loss of relativity between the ESRD MCP codes and their outpatient E&M building blocks, RPA continues to believe that the relationship between the family of inpatient dialysis services and the associated E&M service (CPT code 99232, level two

hospital visit) that serves as its primary practice expense component code continues to be increasingly misaligned. Recall that in the Medicare Physician Fee Schedule Final Rule for CY 1995 published on December 8, 1994, and in Transmittal 1776, Change Request 2321 of the Medicare Claims Manual, HCFA/CMS states in both documents that:

“We will bundle payment for subsequent hospital visits (CPT code 99231 through 99233) and follow-up inpatient consultations (CPT codes 99261 through 99263) into the fee schedule amounts for inpatient dialysis (CPT codes 90935 through 90947).”

While follow-up inpatient consultations (CPT codes 99261 through 99263) have been deleted from the fee schedule for payment purposes, the subsequent hospital visit codes are of course still part of the fee schedule. However, as indicated in Addendum B for the 2021 fee schedule, the PE RVUs for CPT code 90935 (inpatient hemodialysis, single evaluation, which serves as the anchor for the inpatient dialysis code family) will be 0.53, while the PE RVUs for CPT code 99232 will be 0.58, even though as the Agency noted above, payment for subsequent hospital component codes is supposed to be bundled into the payment for inpatient dialysis. Thus, the PE RVUs for inpatient dialysis will be less than that of its component code, and RPA believes that this is a rank-order anomaly that the Agency should correct administratively.

RPA therefore urges CMS to revise the practice expense values for the inpatient dialysis code family to ensure that they are not less than that of its component codes.

Proposed 2021 Conversion Factor and Budget Neutrality

Like many societies in organized medicine, RPA is deeply concerned about the significant reduction in the conversion factor (CF) for CY 2021 resulting from valuation refinements and other policy changes that invoked budget neutrality. We fully support the proposals for valuation changes in service code families such as for E&M services, vaccinations, and specific to kidney disease care, the ESRD MCP code family. RPA believes the RVU refinements for those code families are overdue and make sense for the Medicare program longitudinally and on a macro level, and thus should be maintained.

That said, the drastic cut in the CF will have a profoundly adverse impact on the care provided to many Medicare beneficiaries, and the specialists and non-E&M physician disciplines rendering those services. Accordingly, RPA urges CMS in the strongest terms to take all administrative measures at its disposal to mitigate the reduction in the CY 2021 CF.

RPA urges CMS to identify and take all administrative steps possible to alleviate the proposed reduction in the 2021 CF, while upholding the proposed valuation refinements outlined in the rule.

Inclusion of Single Visit MCP Codes on Approved Telehealth List

In Table 12 of the proposed rule, CMS summarizes its proposals for revising the approved telehealth services in Medicare. Section 3 of the table includes the codes that it is not proposing to add to the approved telehealth list; the single visit outpatient dialysis codes (CPT codes 90953, 90956, 90959, and 90962) are included in section 3. RPA agrees with CMS' decision to not add these codes to the approved telehealth list after the public health emergency (PHE) concludes. We believe that the standard of care for monthly dialysis services is that the Medicare beneficiary with ESRD should be seen by their nephrologist or associated advanced practitioner at least monthly on a face-to-face basis if possible. Thus, the need to have the single visit codes on the approved telehealth list would be removed.

RPA supports CMS' plan to remove the single visit monthly dialysis codes from the approved telehealth list following the public health emergency.

Coverage and Pricing for Percutaneous Creation of an Arteriovenous Fistula

The proposed rule creates two new HCPCS codes (G2170 and G2171) to describe the two modalities for percutaneous creation of an arteriovenous fistula (pAVF) used for dialysis vascular access, in order to address a gap in proper coding for these services. Previously, CMS has provided coverage for these services in the ambulatory surgical center (ASC) setting of care, but that coding did not reflect the resource costs associated with the physician portion of the service. Additionally, the burdens created by the COVID-19 PHE exacerbated patient access issues in obtaining dialysis vascular access care. RPA sought coverage for these services prior to the PHE and reiterated our request once the PHE-related concerns heightened, and thus we are deeply appreciative of CMS' actions in this area.

RPA is concerned with the proposal to maintain contractor pricing for these services, and we urge CMS to reconsider and set values for the services in the fee schedule. Delegating pricing to the contractors would introduce substantial variability and unpredictability in reimbursement for these services, and thereby would likely drastically limit their adoption and use among practices providing vascular access services. Such a restriction would seemingly be counter to CMS' objectives in creating the codes, to expand access to pAVF services.

RPA fully supports CMS' decision to create new HCPCS codes for the two modalities for percutaneous creation of an arteriovenous fistula (pAVF) used for dialysis vascular access. We urge CMS to reverse its decision to maintain contractor pricing for the services and urge CMS to assign values for these services in the fee schedule.

Proposed Removal of NCD #110.14 for Apheresis

In the rule, CMS proposes to remove National Coverage Determination #110.14 for apheresis (Therapeutic Pheresis), developed in 1992. The Agency notes in the rule that this NCD predates the current NCD public notice standards, and that no evidence review was published in support of the NCD. RPA acknowledges that these concerns are a legitimate rationale for reconsidering the NCD.

However, RPA also believes that the Medicare beneficiaries for whom therapeutic pheresis is prescribed discernibly benefit from its use. There is a clear cohort of patients that are dependent on this therapy on a chronic basis to remain functional and barriers to accessing this service would be detrimental to their care. Further, with regard to the evidence, we believe that there is sufficient evidence for its use as a potential frontline therapy for conditions such as myasthenia gravis crisis, Waldenstrom's with neurologic sludging symptoms, acute Goodpasture's, and multiple myeloma with acute kidney injury (AKI). While there is a lesser degree of evidence in its use as a palliative or rescue therapy for diagnoses such as chronic myasthenia gravis, chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), or stiff person syndrome, for those beneficiaries with these conditions, it is still a valuable part of their care. Thus, RPA posits that apheresis services have both primary, evidence-based uses and secondary, palliative uses for which apheresis should be within the treatment armamentarium of the nephrologist.

RPA recognizes that the Agency is not proposing to eliminate coverage but instead to leave it to contractor discretion. We believe this would unnecessarily compromise access to apheresis services by fostering inconsistent and variable coverage across the country based on the contractor for a specific region, leading to disparities in care. Rather than removing the NCD, RPA urges CMS to keep the NCD in place and proceed with a process to update the policy according to the current NCD public notice standards that includes a robust evidence review.

RPA urges CMS to keep NCD #110.14 for Apheresis in place and to embark on a public notice and review process that evaluates the current level of evidence for covering this service.

Refinements to the QPP for 2021

As the leading nephrology organization in quality measure development in kidney care and an early adopter of quality measures in nephrology, RPA has played a central role in navigating the integration of quality measures in Medicare incentive programs. We have been an active participant in the Medicare Quality Payment Program (QPP), as evidenced by our development of the only specialty society owned nephrology-specific CMS-approved Qualified Clinical Data Registry (QCDR). RPA continues to be deeply troubled by the decision made as part of the 2020 fee schedule/QPP to eliminate the nephrology measures from the QPP, which we believe was short-sighted and misaligned with the effort to provide the highest possible level of care to patients with

kidney disease especially in light of the Administration's Advancing American Kidney Health Initiative. That said, to continue to positively contribute to the dialogue relating to quality measurement and kidney disease, we offer the following comments on the MIPS Value Pathway (MVP), the Merit-based Incentive Payment System (MIPS), and Promoting Interoperability.

MIPS Value Pathway (MVP)

- RPA commends CMS for making the MVP program optional for eligible providers.
- RPA supports the delay in launching the MVP program, but urges further delay until 2023 to provide adequate time for both physicians and electronic health record vendors to adapt their workflows and systems to meet the new needs of the disease-specific pathways and activities implied by the combined quality measure and improvement activities. RPA also recommends that CMS first develop a pilot program before rolling out the program to the entire country.
- As the 2020 final rule eliminated renal measures from MIPS leaving no relevant measures for nephrology, we implore CMS to work with the community to develop meaningful nephrology-specific quality measures that focus on the critical processes and outcomes of treating patients with kidney disease. For example, a nephrology MVP could focus on Stage 4 chronic kidney disease (CKD) through early end-stage renal disease (ESRD) that mimics the measures, structure, and goals of the RPA's proposed Incident Dialysis Model that was presented to and accepted by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). Furthermore, CMS must provide clarification and recognition that dialysis patients are to be excluded from performance improvement (PI) measures for physicians since they do not control the EHR used for patient documentation in most dialysis facilities.
- RPA opposes CMS' proposal to layer population health / administrative claims-based measures into MVPs, using current cost/administrative claims measures. Many of the existing administrative claims measures have not been tested at the physician level and are based on retrospective analyses of claims and do not provide sufficient granularity for physicians to make improvements in practice. CMS also prohibits specialty societies from developing and proposing administrative claims measures. Once appropriate cost measures are determined, CMS must make cost data is easy to access, timely, and in a format understandable to typical small and medium sized medical practices.

Merit-based Incentive Payment System (MIPS)

- RPA appreciates CMS' recognition of the increased challenges providers' face in light of the COVID-19 pandemic and supports the reduction of the MIPS performance threshold from the 60 points finalized last year to 50 points in 2021.

- RPA supports the proposed doubling the complex patient bonus for the 2020 performance period.

Promoting Interoperability

- RPA supports the proposal to maintain the Electronic Prescribing objective's Query of Prescription Drug Monitoring Program (PDMP) measure as optional for the performance period in CY 2021.
- RPA supports the proposal to increase the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs.

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 Medicare Fee Schedule and Quality Payment Program. 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 "Jeffrey A. Perlmutter" with a stylized flourish at the end.

Jeffrey A. Perlmutter, MD
President