



September 6, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-1770-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Re: CMS–1770–P: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

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 2023 Medicare Fee Schedule proposed rule. Our comments will address the following issues:

- **Proposed 2023 Fee Schedule Conversion Factor**
- **Valuation of Specific Codes**
 - **Percutaneous Arteriovenous Fistula Creation (CPT Codes 368X1 and 368X2)**
- **Evaluation and Management (E&M) Visits**
 - **Determining Visit Level for Inpatient E&M Services**
 - **Split/Shared Services**
- **CY 2023 PFS Impact Discussion and Cuts Due to Clinical Labor Input Revisions**
- **Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services**
- **Refinements to the QPP for 2023**

Proposed 2023 Fee Schedule Conversion Factor

RPA shares the concerns of the entire house of medicine regarding the now-ongoing reductions in Medicare Part B reimbursement due to the cut in the conversion factor (CF), owing to the requirement for budget neutrality in the CF formula. As noted last year in our comments on the 2022 fee schedule, RPA recognizes that the CF reductions and the use of budget neutrality are the result of Congressional actions and thus it is not within the Agency's prerogative to unilaterally address these formula-driven cuts.

However, there is great urgency in the need to address budget neutrality reductions, and we do believe that CMS has a role to play in eliminating these cuts, both for 2023 and beyond. The CMS mission statement states that *"CMS will strengthen the health care services and information available to Medicare and Medicaid beneficiaries and the health care providers who serve them."* Annual cuts in the CF for services provided to Medicare beneficiaries serves to weaken health care services and the health care providers rather than strengthen them. As such, RPA would posit that embedded in the Agency's mission statement is an obligation to not only identify and take all administrative steps possible to alleviate the proposed reduction in the 2023 CF, but to work with Congress to address the budget neutrality issue for future years. **RPA urges CMS to not only take all administrative steps available to them to address the CF cuts, but to work with Congress to find an alternative to the use of budget neutrality in the fee schedule payment formula.**

Valuation of Specific Codes

Percutaneous Arteriovenous Fistula Creation (CPT Codes 368X1 and 368X2)

CMS proposes in the rule to delete HCPCS codes G2170 (percutaneous arteriovenous fistula—pAVF—creation, direct, any site, by tissue approximation using thermal resistance energy) and G2171 (pAVF creation, direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy) and replace them with CPT codes 368X1 and 368X2, respectively, as recommended by the RUC. These technologies represent a significant advance in the placement of AV fistulas, and RPA supports their transition to CPT and inclusion in the fee schedule.

Regarding valuation of the codes, CMS expresses disagreement with the RUC recommendations for both services, proposing a work RVU of 7.20 (down from the RUC recommendation of 7.50) for CPT code 368X1, and a work RVU of 9.30 for CPT code 368X2 (down from 9.60). The RUC recommended values were based on robust and clinically relevant surveys, and utilized the 25th percentile value emanating from the surveys for both codes. The rationale CMS has offered for reducing physician work RVU's from the RUC recommended values related solely to comparing physician time with other physician services. The RUC recommendations account not only for physician time but also for the complexity and intensity of these procedures relative to comparable services in a way that the CMS proposed values do not. CMS's proposed values therefore do not accurately reflect relativity necessary in a relative value scale – the basis of the entire fee schedule. A decision to propose values below the 25th percentile should not be

arbitrary but utilize the same methodology applied to other services subject to the relative value scale. **RPA strongly disagrees with CMS’ proposal to reduce the values for 368X1 and 368X2, and urges CMS to utilize the RUC-recommended values for both services.**

On an equipment input that is specific to code 368X1, CMS proposes to specify use of an ultrasound room rather than an angiography room in the development of the practice expense values for that service. In our view this is incorrect, as 368X1 typically infers inclusion of a balloon angioplasty among the performed procedures, and in the experience of our interventional nephrologists the appropriate venue when a balloon angioplasty is performed is always an angiography room. **RPA urges CMS to revise the equipment inputs for service code 368X1 to reflect use of an angiography room rather than an ultrasound room.**

Evaluation and Management (E&M) Visits

Determining Visit Level for Inpatient E&M Services

In the proposed rule, CMS outlines its plans to adopt the general CPT framework for Other E&M visits (which include hospital inpatient, hospital observation, emergency department, nursing facility, home or residence services, and cognitive impairment assessment). One of the primary features of this framework is that practitioner time or medical decision making (MDM) would be used to select the E&M visit level, to be in alignment with the structure in place since 2021 for outpatient office services. RPA is cognizant that CMS is not obligated to accept CPT recommendations, and we accordingly commend the Agency for this determination. **RPA commends CMS for adopting CPT’s recommendations in this area and aligning the process for determining inpatient E&M visit levels with that previously established for outpatient E&M services.**

Split/Shared Services

On split/shared services provided jointly by a physician and an advanced practitioner, the proposed rule includes discussion of the Agency’s proposal for CY 2022 to base the definition of ‘substantive portion’ solely on time (meaning that whichever provider performed more than half of the service as measured by time would bill for the service, regardless of medical decision making—MDM), and the subsequent determination to delay implementation of the revised definition until CY 2023. CMS in this rule proposes to further delay the time-only basis for substantive portion until CY 2024. RPA appreciates the Agency’s flexibility and responsiveness to community input.

However, RPA remains deeply troubled by the proposal’s continued inclusion in fee schedule rulemaking for any year. As RPA noted in previous comments, basing the definition solely on time diminishes both the importance of MDM and the physician’s experience, fund of knowledge and judgement that inform the leadership role needed in making decisions about patient care, much of which requires review and synthesis of multiple sources of information. Additionally, basing the definition of ‘substantive portion’ of

a visit solely on time infers that all thinking and decision making must be done in front of the patient; this is wholly inaccurate and does not nearly reflect the realities of 21st century medical practice or health care delivery.

In short, RPA strongly believes in the primacy of MDM over time as the most important element of patient care and that there is no valid justification for assigning insufficient importance to MDM in defining the substantive portion of a shared visit. This is especially true in the care of Medicare beneficiaries with kidney disease. Though the nephrologist's direct time with a patient may be less than 50% of the total time spent, nephrologists are responsible for the substantive majority of the decision-making activities most critical to that patient's care – for instance helping a patient finalize a decision to pursue a home (rather than in-center) dialysis modality, irrespective of who engages in which part and how much of the conversation.

Further, in the context of the current movement towards value-based care delivery systems that are being developed and refined to account for finite physician workforce resources, the proposed definition of substantive portion seems to ignore the nephrologist-led, team-based care models that are foundational underpinnings of CMS' kidney payment models. These models were developed to help enable nephrologists and other kidney care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stages 4 and 5 and ESRD, to delay the onset of dialysis, and to incentivize kidney transplantation. RPA would posit that at least in the treatment of kidney care, determining split/shared services billing based solely on time is a penny-wise, pound-foolish policy that will adversely affect patient care. **RPA strongly urges CMS to permanently withdraw its proposed definition of substantive portion of a split/shared visit and explore an alternate path that sufficiently accounts for the primacy of medical decision making in such a definition.**

CY 2023 PFS Impact Discussion and Cuts Due to Clinical Labor Input Revisions

In the proposed rule, CMS refers to use of updated clinical labor inputs and its impact on categories of procedures, noting the decision beginning with the CY 2022 cycle to use a multi-year transition that would “help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year.”

While RPA acknowledges the need to use updated data, we also believe the framework described above minimizes the impact on the affected procedures, the availability of which in the physician office setting are facing an existential crisis. The reason CMS is using a transition for the changes is that a minimum 20% reduction in value for these services (in addition to what might happen more broadly with the CF) would be catastrophic for Medicare beneficiaries who rely on the availability of these services.

In kidney care, the family of services most affected is the dialysis circuit code family of services (CPT codes 36901-36909). These codes represent services that play a critically important role in maintaining and

repairing a dialysis patient's vascular access, services that should be obtainable in as many settings of care as possible. However, if the transition is to continue for three more years, closure of many physicians' office-based labs in which these services are provided are all but certain. Additionally, threatening the viability of vascular access care for dialysis patients at a time when improved kidney health is an area of emphasis for CMS (as evidenced by the mandatory and voluntary kidney payment models in various stages of implementation by the CMS Innovation Center) runs counter to not only CMS' organizational priorities but also and more importantly, negatively impacts the care provided to Medicare beneficiaries with kidney disease. **RPA urges CMS to pause the transition underway to implement updated clinical pricing inputs, and develop a revised proposal based on community input that does not disproportionately impact the non-facility site of service and which ensures patient access to care.**

Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

In the proposed rule, CMS notes that current policy provides for payment of an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery. This is because the dental service is inextricably linked to, and substantially related and integral to the clinical success of the renal transplant. Subsequently, the rule goes on to state that:

However, we believe that comprehensive workups prior to renal transplant surgery, including related dental examinations, can occur in either the inpatient and outpatient setting. As such, we are proposing to provide Medicare payment for oral or dental examinations performed as part of a comprehensive workup prior to renal transplant surgery when these services occur in either the inpatient or outpatient setting,

RPA strongly supports the Agency's proposal to pay for pre-renal transplant surgery dental services in either the inpatient or outpatient setting. We commend the Agency for its forward thinking in seeking ways to promote improved dental health to advance the success of kidney transplants.

Further, RPA believes that access to periodic dental care could be greatly beneficial to all Medicare ESRD beneficiaries, including those soon to be enrolled in the new Part B-ID program for immunosuppressive drug coverage. Regular dental care can identify and reduce the occurrence of infections and cardiovascular complications that adversely affect dialysis care, transplant success, and overall good kidney patient health. We concur with Kidney Care Partners (KCP) and others in the kidney community that given that ESRD beneficiaries make up only 1% of the entire Medicare patient population, providing that coverage to that subset of Medicare patients would not profoundly burden the system financially and could provide cost savings in prevention of the not uncommon array of complications noted above. That said, we would recommend that CMS provide this funding through Medicare Part A (the rule notes the coverage is available through both Parts A and B) so as to not exacerbate conversion factor shortfalls. **RPA strongly supports CMS' proposal to provide coverage for inpatient or outpatient oral or dental**

examinations prior to renal transplant surgery. Further, we urge the Agency to extend this coverage to all ESRD and Part B-ID beneficiaries, and to fund this additional coverage through Medicare Part A.

Refinements to the QPP for 2023

Under the umbrella of refinements to the physician Quality Payment Program (QPP) for 2023, RPA offers comments in the areas of the Quality Category, the new kidney health MIPS Value Pathway (MVP), and the Promoting Interoperability Performance category.

New Quality Measures

RPA appreciates the inclusion of new nephrology-related quality measures in the QPP. RPA strongly supports the inclusion of the Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy measure, as this measure is aimed at increasing the number of patients with chronic kidney disease (CKD) and albuminuria who are prescribed ACE inhibitor or ARB therapy. ACE inhibitors and ARBs are recommended as preferred agents for diabetic kidney disease and nondiabetic kidney diseases with proteinuria (albuminuria), even in the absence of hypertension. In these diseases, they lower blood pressure, reduce proteinuria (albuminuria), slow the progression of kidney disease, and likely reduce CVD risk by mechanisms in addition to lowering blood pressure.

RPA also supports the inclusion of the Kidney Health Evaluation measure in MIPS, as the identification of kidney disease is critical to slowing its progression.

Nephrology Measure Set

RPA also appreciates the inclusion of new quality measures in the MIPS nephrology measure set. While RPA believes the Screening for Social Drivers of Health measure is most appropriate for primary care, there may be instances where social drivers of health are linked to disparities in kidney care, and therefore supports its inclusion in the nephrology measure set. As noted above, RPA supports the inclusion of the Kidney Health Evaluation measure.

High Priority Measures

RPA appreciates CMS' expansion of the definition of a high-priority measure also to include health equity-related quality measures.

Removal of Measures

RPA supports the replacement of Diabetes: Medical Attention for Nephropathy with Kidney Health Evaluation.

Data Completeness Threshold

RPA appreciates CMS' decision to maintain the data completeness threshold at 70% for 2023 and encourages the Agency to continue at that level for the 2024 performance period.

Optimal Care for Kidney Health MVP

RPA appreciates the creation of a more nephrology-specific MVP. However, RPA does have concerns regarding the included cost measures. RPA is concerned that the cost measures – Acute Kidney Injury Requiring New Inpatient Dialysis and Total Per Capita Cost – hold the nephrologist responsible when there are a multitude of providers involved in patient care. In particular, as RPA has noted in previous comments regarding Acute Kidney Injury Requiring New Inpatient Dialysis, we believe that appropriate clinician attribution is problematic. Patients requiring dialysis for AKI usually have multiple medical problems and complications, and multiple providers and consultants. For the vast majority of patients, the management of AKI accounts for only a small fraction of the inpatient cost of care. It is rare that the nephrologist has any substantial control over the total cost. Similarly, for outpatient care, AKI patients often require multiple non-renal services which are outside the control of the nephrologist. Finally, RPA is concerned that holding nephrologists responsible and accountable for these costs may have the unintended consequence that will result in nephrologists hesitant to initiate dialysis in AKI patients – thus potentially delaying access to clinically necessary care with prolongation of hospitalization and/or other adverse outcomes.

Promoting Interoperability

RPA supports the inclusion of Query of Prescription Drug Monitoring Program (PDMP) as a required measure as long as appropriate exclusions are in place. However, RPA believes that for the first year of required reporting it should be limited to Schedule II only.

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. 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,



Timothy A. Pflederer, MD FASN FASDIN
RPA President