August 31, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-1749-P
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1749-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 2022 ESRD PPS/QIP Proposed Rule, including provisions affecting the ETC Mandatory Kidney Payment Model. Our comments address the following issues:

- **QIP Exclusion for Palliative Dialysis Patients**
- **Proposed Changes to ETC Model, including:**
  - Attribution of living donor beneficiaries to the nephrologist (Managing Clinician) with the most claims in the previous 365 days;
  - Addition of nocturnal in-center dialysis to the calculation of the home dialysis rate for ESRD facilities not owned in whole or in part by an LDO or Managing Clinicians;
  - Exclusion of beneficiaries with a diagnosis of vital solid organ cancer from the calculation of the transplant rate;
  - Increasing achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas;
  - Use of proposals related to health equity to address disparities in home dialysis and transplant rates;
  - Creation of a process by which CMS would share certain model data with ETC Participants;
• Establishment of waivers through which managing clinicians could provide kidney disease education (KDE) via telehealth, and allowing managing clinicians to waive the beneficiary coinsurance for KDE;

• Requests for Information (RFIs) to promote PD catheter placement.

• Request for Information on Pediatric Dialysis Payment

**QIP Exclusion for Palliative Dialysis Patients**

As noted in the proposed rule, similar to how the Standardized Readmission (SRR) clinical reporting measure is proposed to be suppressed during the COVID PHE because of the increased hospitalization rate and mortality of dialysis patients infected with SARS-CoV-2, the RPA requests that henceforth dialysis patients who are seriously ill and receiving palliative dialysis be excluded from the ESRD QIP facility measure data. Palliative dialysis is indicated for patients with severe comorbidities and a life expectancy of less than one year.1,2 The RPA request is consistent with a recognition in the proposed rule that “vulnerable” patients who are at risk of complications be accorded individualized, value-based treatment to improve their care.

The RPA proposes that CMS use the following criteria to identify seriously ill dialysis patients to be excluded from ESRD QIP facility measure data. The RPA would welcome the opportunity to work with CMS to develop an alternate set of quality metrics for these seriously ill dialysis patients.

1. Referred for hospice care and/or
2. Having chart documentation of the institution of palliative dialysis and
3. Having an advance care plan with treatment limitations such as a living will and/or medical orders such as the Physician Orders for Life-Sustaining Treatment (POLST) order set that includes do not resuscitate (DNR), do not intubate, and do not transfer to the intensive care unit (ICU) combined with at least two of the following indicators of poor prognosis:
   a. Cognitive impairment with moderate or severe dementia (article attached)
   b. Age 75 years or greater
   c. Frailty with a score on the CFS of equal to or greater than 53

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RPA urges CMS to create an exclusion from the QIP facility measure data for palliative dialysis patients.

Proposed Changes to ETC Model

Proposal for attributing living organ donors to Managing Clinicians

In the proposed rule CMS outlines its plans to attribute pre-emptive living donor transplant (LDT) Beneficiaries to the Managing Clinician with whom the beneficiary has had the most claims during the 365 days prior to the transplant date, with the proviso that if no Managing Clinician had the most claims within 365 days, the LDT beneficiary would be attributed to the Managing Clinician with the most recent claim during that period. **RPA supports CMS’ proposal as we believe this is a straightforward and easily understandable method for determining LDT beneficiary attribution in the ETC program.**

Addition of nocturnal in-center dialysis to the calculation of the home dialysis rate for ESRD facilities not owned in whole or in part by an LDO or Managing Clinicians

Like CMS, RPA believes nocturnal dialysis offers a wide range of benefits to Medicare ESRD beneficiaries. These include the clinical benefits of slow dialysis that more closely resembles the process of a native kidney, the societal benefit to patients of being more conducive to employment and other normal life activities, and the access it affords to patients who might otherwise have that opportunity due to limited financial resources, housing insecurity, lack of social support, or personal preference, as CMS notes in the proposed rule.

As a result, we are puzzled by the profound limitations outlined in the rule that we believe would disqualify the application of the proposal to all but a few Medicare ESRD beneficiaries. Given that according to the Medicare Payment Advisory Commission (MedPAC) the two largest dialysis providers in the U.S. accounted for three-quarters of facilities and Medicare treatments in 2018, this infers that absent any other factor the expanded availability of nocturnal care would be unavailable to 75% of Medicare beneficiaries. Further, the additional exclusion of facilities owned wholly or in part by Managing Clinicians eliminates those providers not affiliated with the two largest dialysis organizations but whom have joint venture ownership agreements with medium and small dialysis organizations in their regions. Thus, the actual percentage of the nation’s dialysis patients potentially adversely affected by the proposed restrictions is discernibly higher.

Accordingly, RPA believes the limitations are illogical and counter to the presumed intent of the provision (to promote the availability and use of nocturnal dialysis). If policymakers and the kidney community believe making nocturnal dialysis more widely available is a positive change and a step forward, it would seem that its use should be encouraged rather than limited. We would also note that since the ETC is already limited to 30% of dialysis organizations and Managing Clinicians, utilization of nocturnal dialysis will already be relatively finite regardless of the proposed limitations; a more robust assessment of its benefits and challenges could be
performed if it were more broadly accessible than if the LDO’s and Managing Clinicians were excluded. For these reasons, RPA urges CMS to remove the exclusion preventing LDO’s and facilities owned wholly or in part by Managing Clinicians from providing nocturnal dialysis for the purposes of the home dialysis rate calculation.

Exclusion of beneficiaries with a diagnosis of vital solid organ cancer from the calculation of the transplant rate

CMS includes in the proposed rule an exclusion from the calculation of the transplant rate for beneficiaries with a diagnosis of, and who are receiving treatment with chemotherapy or radiation for, vital solid organ cancers. RPA appreciates this consideration but would also note that if the solid organ cancer was treated within the previous five years the patient cannot be waitlisted. Given that, RPA would urge CMS to expand the exclusion to include patients receiving such treatment within the last five years.

Increasing achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas

In updating the performance payment adjustment, CMS solicits comments on its proposal to increase achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas (CGAs) every two measurement years (MYs), beginning in MY3 (2022). RPA appreciates the difficulty in developing proposals of this nature and scale, as well as CMMI’s need to be mindful of its fiduciary responsibilities in such matters. Given recent increases in home dialysis rates and that the 10 percent increase is over every two MYs, that threshold appears to be reasonable. However, we concur with the comments of Kidney Care Partners (KCP) and others that use of CGAs as the baseline for determining achievement benchmarks may unintentionally establish a disincentive to provide the highest quality of care possible in the CGAs. Alternatively, we support KCP’s recommendation to utilize population-weighted benchmarks upon which to base the achievement benchmarks. RPA believes that the 10 percent increase in achievement benchmarks over a two-year period is a reasonable threshold. However, we would urge the Agency to utilize population-weighted benchmarks rather than the CGAs as a comparator to remove any potential inadvertent disincentive to providing the most effective and highest quality care possible in the CGAs.

Use of proposals related to health equity to address disparities in home dialysis and transplant rates

The proposed rule outlines CMS’ plans within the ETC to use two provisions to address disparities in home dialysis and transplant rates through the ETC Model’s benchmarking and scoring methodology. The first would add a Health Equity Incentive to the improvement scoring methodology for both the home dialysis rate and the transplant rate under which participants

demonstrating significant improvement in home dialysis or transplantation among their Medicare/Medicaid dual-eligible or low-income-subsidy (LIS) beneficiaries could earn additional improvement points; the second would stratify achievement benchmarks based on the number of dual-eligible or LIS beneficiaries so that practices with high volumes of these patients would not experience inappropriate financial penalties. RPA believes these are positive steps to address inequities in care delivery and CMS is to be commended for proceeding in this manner. **RPA supports CMS’ proposals to seek improvement in home dialysis and transplantation rates through the use of a Health Equity Incentive, and to stratify achievement benchmarks for participants with high volumes of dual-eligible or LIS patients.**

**Creation of a process by which CMS would share certain model data with ETC Participants**

In the rule, CMS proposes to establish a process for the Agency to share certain beneficiary-identifiable and aggregate data with ETC Participants pertaining to their participation in the ETC Model. CMS notes in the rule that the Agency “believes that ETC Participants need this data to successfully coordinate the care of their ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries; to succeed under the ETC Model; and to assess CMS’s calculations of the individual ETC Participant’s PPA for a given PPA Period.” Access to beneficiary-identifiable data especially concerning transplant waitlist candidates has been a primary concern for RPA members participating in the mandatory models, and therefore RPA fully supports this proposal and commends the Agency for establishing this process.

Further, we appreciate CMS’ approach in both requiring the ETC participant to sign a data-sharing agreement to gain access to the data, but not requiring the participant practice to formally request the data. RPA concurs with the Agency that mandating a request for the data would not meaningfully impact privacy or security concerns, and would create an administrative burden for all parties that is unnecessary. **RPA supports CMS’ decision-making and proposed process for sharing beneficiary-identifiable and aggregate data with ETC Participants.**

**Establishment of waivers through which managing clinicians could provide kidney disease education (KDE) via telehealth, and allowing managing clinicians to waive the beneficiary coinsurance for KDE**

Outlined in the rule are proposals to allow kidney disease education (KDE) services to be furnished to certain beneficiaries via telehealth in a manner that is more flexible than that required under existing telehealth requirements, and to permit the reduction or waiver of coinsurance for KDE services, with both waivers available beginning in MY3. RPA wholly supports these proposals. Expansion of telehealth flexibilities has been a high priority issue for RPA for several years, as we believe that elimination of originating site and geographic restrictions (with guardrails) can only benefit patient care and more effectively utilize the nephrologist workforce. Regarding the waiver of coinsurance for KDE services, RPA identified this as a concern shortly after its implementation as part of the 2011 Medicare Fee Schedule
and has raised this issue with policymakers ever since. **Accordingly, RPA completely supports implementation of both KDE-related waivers included in the proposed rule.**

**Request for Information (RFI) to Promote PD Catheter Placement**

The ETC section of the proposed rule includes a request for information (RFI) regarding current barriers to peritoneal dialysis (PD) catheter placement, and opportunities to promote these services. CMS notes stakeholder input on some of the frequently cited barriers to PD catheter placement, including the lack of availability of vascular surgeons to perform PD catheter placements, lack of appropriate operating room time, and a lack of training on PD catheter placement for vascular surgeons. RPA would also add to this list that many of the prospective candidate patients are either not yet eligible for Medicare or are uninsured, and that there is little incentive for hospitals or other facility settings to address the issue.

RPA does believe that that Innovation Center should address PD catheter placement (and share their experience with the Hospital and Ambulatory Policy and Chronic Care Policy Groups within the Center for Medicare). Among the payment structures RPA would urge the Innovation Center to explore would be retroactive payments for placement of PD catheters that are proven to have been successful over time (such as for patients who remain on PD home dialysis for six months), or establishment of a bonus structure similar to that set forth in the Kidney Care Choices (KCC) Voluntary Payment Model. RPA believes that the cost/benefit analyses and other market-based rationales that led CMMI to test the viability of a transplant bonus in the KCC would apply in the context of the ETC model as well and may hold lessons for Medicare payment more broadly. To the extent that CMS pursues innovative policies for promoting PD catheter placement, we urge the Agency to not exclude pediatric patients from such policies. **RPA urges CMMI to address PD catheter placement and consider possible alternate payment structures such as retroactive payment for successful placement or a bonus akin to the KCC transplant bonus; such innovations should include pediatric patients.**

**Request for Information on Pediatric Dialysis Payment**

The proposed rule solicits responses to a series of questions regarding pediatric dialysis payment, and RPA fully supports the recommendations offered by the American Society of Pediatric Nephrology (ASPN) in their comments on the rule. RPA commends the Agency for issuing the RFI, as any perceived notion that pediatric patients are ‘small adults’ and that the adult dialysis payment structure can largely be applied to pediatric patient care with only minor modifications is untrue and should be abandoned.

While RPA concurs with the entirety of ASPN’s suggestions, we would like to specifically call out the following points:

- **The current total cost of pediatric dialysis care is not covered by the current pediatric dialysis payment system**: There is a substantial shortfall between total current cost and total current payment, as demonstrated by ASPN’s reference to pediatric dialysis.
provided by a large dialysis organization (LDO), where in what would be expected to be a favorable economic situation, pediatric in-center hemodialysis costs twice as much as dialysis care delivered at adult in-center units. CMS’ payment methodology for pediatric dialysis needs to account for the unique staffing and supply-related needs that are specific to the pediatric patient population.

- **Use of a blend of age, weight, and the pediatric-specific comorbidities suggested by ASPN would be a more representative process for determining pediatric composite rate costs than duration of treatment:** Acknowledging that use of a simple proxy like duration of treatment is administratively desirable, RPA would posit that the absence of granular specificity in the process of determining pediatric dialysis costs is the reason that CMS felt compelled to issue an RFI, i.e., a more detailed approach is necessary to create a more accurate and equitable pediatric dialysis payment system.

- **The ‘small numbers’ concerns facing pediatric dialysis care should not be a hindrance to development of a fairer and more appropriate payment system:** Even though CMS’ own pertinent Technical Expert Panel (TEP) from December 2020 determined that pediatric patients make up only 0.14% of the Medicare ESRD population, the fact is that these patients are Medicare beneficiaries, and shortcomings in the relevant payment system that can compromise the ability of pediatric nephrologists and other members of the pediatric dialysis caregiver community must be addressed and corrected. Pediatric patients potentially have the longest survival time with ESRD, so they should have access to the most appropriate care to optimize growth and development, reduce morbidity and minimize future healthcare costs.

- **Revisions to the pediatric cost report would enhance CMS’ capability to capture pediatric dialysis expenses and provide more appropriate reimbursement for the associated care:** RPA believes that ASPN’s proposed revisions to the patient age group categories are rationale, and similarly we believe that the proposed changes affecting staffing classifications and supplies if implemented would improve the accuracy of pediatric dialysis cost reporting and subsequent reimbursement.

Again, we are greatly encouraged by CMS’ effort to gather community input on improving the pediatric dialysis payment system. **RPA urges CMS to implement the recommendations made by ASPN regarding pediatric dialysis payment.**

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 and the ETC Mandatory Kidney Payment Model. 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,

[Signature]

Timothy A. Pflederer, MD FASN FASDIN
RPA President