



September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1693-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

On behalf of Kidney Care Partners (KCP), I want to thank you for providing the opportunity to provide comments on the Proposed Rule entitled “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program” (Proposed Rule).

KCP is an alliance of members of the kidney care community that includes patient advocates, kidney care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.¹

I. KCP supports the implementation of expanding access to home dialysis therapy through the telehealth benefit

KCP supports CMS’s interpretation of the provisions of the Bipartisan Budget Act of 2018 that expand access to home dialysis through the telehealth benefit. KCP has long supported allowing the patient’s home and the dialysis facility to serve as originating sites for home dialysis telehealth services. We believe that the Congressional decision to allow the use of telehealth visits in two months of a consecutive three-month period to qualify as the monthly face-to-face visit (after an initial three-month period) without geographic restrictions will help expand the utilization of home dialysis modalities. This policy will help patients who have difficulty seeing their nephrologists for the monthly in-patient visit.

¹ A list of KCP members is provided in Appendix A.

We also ask that CMS recognize the adoption of mobile and hand-held devices by many patients who might not have a more traditional computer. Specifically, we recommend that CMS allow patients to use these devices to interact with their nephrologist during the monthly face-to-face interactions. There is no technical reason why such devices cannot be equally as effective as traditional computers.

II. KCP supports delaying the implementation date of the evaluation and management (E&M) visit policies.

In response to CMS's request for comments on whether a delay in the implementation date for the E&M visit policies, KCP recommends that CMS delay implementation until at least January 1, 2020, if not longer. In fact, it may be more appropriate not to establish a single implementation date. Rather, we join with physician organizations in asking that CMS coordinate with the AMA CPT Editorial Panel and develop a process and structure that optimally achieves the regulatory relief goals in the area of documentation guidelines, while accounting for the concerns of nephrologists and other physicians regarding the revision of the E&M payment levels. Our member organizations are concerned that more time is needed to educate physicians and their staff, transition clinical workflows, update electronic health record (EHR) templates, and update other documents. More time is also needed to update specific CPT codes as well.

III. KCP recommends that CMS make the E&M service complexity adjuster applicable to nephrologists providing services to CKD patients.

Providing services to beneficiaries with CKD includes a significant percentage of high level E&M services. Nephrologists do a disproportionate number of level 4 and 5 services for their CKD patients. These services are critically important, especially to help patients whose disease is progressing toward kidney failure consider their options for transplant and home dialysis. Thus, KCP supports the proposal to adopt an E&M service complexity adjustment to account for those specialty physicians with disproportionately high percentages of E&M services within their overall Medicare billings and who predominantly treat high complexity chronic conditions. Although the complexity adjuster alone is not sufficient to solve the larger problems created by the policy, we ask that in the final rule CMS clearly state that this adjuster will apply to the services provided by nephrologists to CKD patients, which are not included in the current list in the Proposed Rule.

IV. KCP encourages that CMS proceed cautiously with the revisions to the E&M visit policy and reduce the burdens created by documentation requirements, consistent with the Impact of Evaluation and Management Visit Policies on Chronic Kidney Disease Care

Consistent with our previous comment letters, KCP strongly supports CMS's efforts to put Patients over Paperwork and reduce administrative burdens on providers. We ask that the following modification be implemented in 2019.

- Allow physicians the option to document visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current guidelines.
- If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients).
- Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient.
- Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty.
- Remove the need to justify providing a home visit instead of an office visit.
- Eliminate the requirement that teaching physicians have to enter a separate note in the medical record.

KCP is also concerned that the proposal to designate a single payment amount for E&M levels 2 through 5 will adversely affect the care provided to CKD patients and run counter to efforts to delay progression to ESRD and dialysis for patients whose disease state worsens. The same single flat fee for E&M levels 2 through 5 undervalues the physician work and expertise associated with caring for these patients. As the Secretary has indicated, care coordination with this population, especially as they transition from CKD to ESRD and are working to select the appropriate modalities and/or prepare for transplant. While CMS suggests that nephrology would have minimal change in overall payment under the E&M policies, according to the American Medical Association (AMA), if this proposal were finalized, nephrologists are projected to be cut by 13 percent.

This proposal if finalized will hurt patients and create a barrier to the Secretary's goals of increasing the number of patients who select home dialysis.

V. KCP recommends policies to expedite the interoperability for the Medicare program.

Care coordination is critically important to this patient population. Thus, we ask that CMS mandate interoperability of health records in the Medicare program. Specifically, in the short-term, CMS should use national patient identifiers and non-proprietary Health Information Exchanges (HIE) to enhance the extraction of data necessary for optimal beneficiary care. We believe doing so would allow the care coordination goals of the Administration to be achieved more quickly by streamlining the process and allow for

simplified systems that are user-friendly and make adoption of interoperability more likely.

VI. KCP's recommendations related the quality programs

KCP has a long history in supporting quality and value-based purchasing. We were the first provider group to actively ask the Congress to establish a value-based purchasing program. We also launched the Kidney Care Quality Alliance (KCQA) to help ensure that there were appropriate and meaningful measures to support the Quality Incentive Program (QIP) used in the ESRD Prospective Payment System (PPS). Consistent with our comments on the ESRD QIP, we support CMS's efforts to focus on meaningful measures that streamline various programs and reduce provider burdens. Also consistent with those comments, we are concerned that there are simply too many measures and too many changes occurring year over year that lead to confusion and additional burdens.

KCP's goal has always been to support measures that can lead to improving patient care and outcomes. Thus, we urge CMS to retain the *Adult Kidney Disease: Blood Pressure Management* and the *Pediatric Kidney Disease: Adequacy of Volume Management* measures. The RPA and ASPN are the stewards of these measures, respectively. CMS's statement that the blood pressure measure has not been update is simply not correct. We also dispute the conclusion that the pediatric measure is a standard of care. Recent clinical literature demonstrates the continued need for this measure as well.² Additionally, removal of this measure would leave only one MIPS measure for pediatric nephrologists.

While we support the efforts to prioritize measures and reduce the reporting burden on physicians, we are concerned that the proposed changes to the quality category measure scoring is premature. Before CMS finalizes a proposal like this one, it should provide additional details about how the tiers will be determined and what the measures will be.

Also consistent with KCP's ESRD QIP comments, we believe it is important to address the issue of topped out measures. Thus, for the physician quality program, we believe that CMS should maintain the topped-out measure removal process. CMS should also provide publicly accessible data demonstrating the topped-out status is stable and do so in a timely manner. It is also important that the process of removing measures remains transparent and subjected to a public comment period.

VII. Use of QIP Measures for AKI Patients

Consistent with our comments in the KCP QIP letter submitted under the ESRD PPS and QIP Proposed rules, we oppose the inclusion of patients with Acute Kidney Injury (AKI) into quality programs that are designed for ESRD patients. As the CMS payment team has

²Hayes, W. & Paglialonga, F. *Pediatr Nephrol* (2018). <https://doi.org/10.1007/s00467-018-3916-4>.

recognized in previous rulemakings, AKI patients are different than ESRD patients because they have not completely and irrevocably lost their kidney function. In AKI, renal replacement therapy is considered to be a temporary treatment. Thus, the same quality metrics that are used for the ESRD population are not appropriate to evaluate the quality of care provided to individuals with AKI who require dialysis.

There is strong consensus among medical experts that ESRD and AKI patients are different, have different treatment goals, and have different outcome goals. The RPA notes in its consensus White Paper entitled, “Acute Kidney Injury Patients Requiring Outpatient Dialysis,” “[t]here is also no evidence that existing ESRD clinical practice guidelines for anemia management, metabolic bone disease, vascular access management, dialysis adequacy, and nutrition are applicable to AKI-D patients.” Given that more work is needed to better understand the progression of AKI, it would not be appropriate to apply the ESRD measures to this group of patients.

The RPA also notes that individuals with AKI “are not in a steady state.” This means that, while the services provided to individuals with AKI may be the same, the frequency with which they are provided those services and the labor required to provide them differ from that required for individuals with ESRD. RPA’s White Paper notes that:

None of these care needs is beyond the capability of most dialysis facilities, but the cumulative degree of care and attention required for the [acute kidney injury requiring dialysis] AKI-D patient typically exceeds that for a patient with ESRD. Additional staff time per patient and specialized staff training may be needed to address the increased needs of these patients.

AKI-D patients may require more frequent lab testing to review kidney function and assess drug levels, nutritional status, infection, and other organ function. They may require antibiotic administration and monitoring for infections unrelated to the dialysis procedure. Intercurrent illness, hospital-based treatments and debility may increase the frequency of missed treatments.

Throughout the CY 2017 Proposed Rule, CMS recognized the real differences in these patient populations as well.

There is much still to learn about the treatment of patients with AKI who require dialysis, including the utilization of renal dialysis services. Because the ESRD QIP measures are based on treatment protocols and scientific literature related to ESRD treatments, and not AKI treatments, it is simply inappropriate to incorporate these patients with the ESRD QIP or any ESRD patient-based quality system.

We agree that these patients should receive high quality care and to that end encourage the Center for Clinical Standards and Quality to work with the Center for

Medicare as it monitors AKI patients through its formal monitoring program to learn more about the clinical needs of this unique patient population.

VIII. Expanding QIP Facility-Based Measurement from ESRD settings to the Physician Office Setting

KCP strongly believes that measures used in any Medicare quality program should be designed to support the reporting of actual performance by the providers being evaluated by them. Thus, we are concerned about the blanket approach proposed that would simply adopt ESRD QIP measures to the physician quality program. The QIP measures were specifically designed, tested, and reviewed for the dialysis facility; not for the physician. While we believe the outcomes should be aligned, the measures themselves need to be designed and tested in a manner that is consistent with the physician-practice in the same way dialysis facility measures are designed and tested in the ESRD facility context. In addition, if these measures were applied to physicians, it would be difficult to attribute facility-level measures to specific physicians. Even though every dialysis facility has a designated medical director, there are specific physician(s) who provide the individualized care to each patient. Attributing facility level performance to specific nephrology providers would be exceptionally difficult if not impossible.

Similarly, it does not seem appropriate to apply the ESRD Five Star ratings to individual physicians, since the facility metrics are measuring multiple health care professionals and the facilities, not an individual physician. Applying the stars to physicians would not represent their actual performance and provide patients with inaccurate and misleading information.

IX. Conclusion

KCP appreciates the opportunity to provide comments on the CY 2019 Physician Fee Schedule Proposed Rule. We look forward to working with HHS on these policies. If you have questions or comments, please contact Kathy Lester at klester@lesterhealthlaw.com or (202) 534-1773. Thank you again for considering our recommendations.

Sincerely,



Allen Nissenson, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
Medtronic
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Otsuka
Relypsa
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare
U.S. Renal Care