



July 25, 2018

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C 20201

RE: HHS Response to PTAC Recommendation on RPA's Incident ESRD Clinical Episode Payment Model

Dear Mr. Secretary,

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 with regard to your response to the Physician-Focused Payment Model Technical Advisory Committee's (PTAC) recommendation on RPA's Incident ESRD Clinical Episode Payment Model.

RPA greatly appreciates your interest in kidney disease care, and the time and effort that you and your staff devoted to reviewing RPA's proposed payment model. We do feel compelled however to provide some clarity on the areas for improvement and further refinement described in your response.

As you are fully aware, PTAC has established certain criteria by which any Physician-Focused Payment Model (PFPM) is assessed. These criteria include the ability to reduce Medicare program costs as well as the need for the proposal to be attractive to small and large practice groups in urban and rural locations. For this latter situation to occur, RPA believed that a fairly straightforward model not requiring creation of an administrative entity while utilizing the existing physician fee schedule was necessary. Regarding Medicare program costs, data exists that the expenditures for incident dialysis patients in the first six months remain disproportionally high compared to prevalent dialysis patients as well as transplanted patients. Further, United States Data Renal System (USRDS) reports clearly demonstrate an adjusted mortality for patients ≥ 65 years of age of >600 deaths per 1000 patient years within the first three months of beginning hemodialysis and ~ 300 deaths per 1000 patient years at six months. This is compared to a rate of 200 deaths per 1000 patient years for the patients <65 years over the same timeframe (*USRDS 2017 Annual Data Report, Volume 2, Chapter 5, Figure 5.3*). The

≥65-year old Medicare beneficiary at the start of dialysis is precisely the patient type our model focuses upon.

Moreover, on the issue of Medicare eligibility, we will cite the June 21 AMA letter to you that states:

When PTAC examined this issue, it found that approximately 45,000 patients who had already been receiving Medicare benefits started dialysis each year. In 2016, Medicare spent an average of \$41,000 on these patients during the six months following initiation of dialysis, which represents about \$1.8 billion in annual Medicare spending. In contrast, the total annual spending for patients currently participating in the CMS Comprehensive ESRD Care model is about \$1.4 billion. This suggests that the RPA APM could have a significant impact.

RPA, like HHS, remains concerned over the potentially small number of beneficiaries attributed to a nephrology practice. We agree that this may become a possible barrier for some nephrology practices. However, we believe this risk could be mitigated by leveraging the existing virtual group framework in place today in the Merit-based Incentive Payment System. The problem with low numbers may involve the potential for outliers, whose costs could be addressed with a truncation methodology similar to what is already in use for other programs. Further, the other issue with small numbers involves cost benchmarking, which we propose to solve by including all incident dialysis patients in an entire Healthcare Referral Region (HRR) or contiguous HRRs until statistical validity is reached.

Regarding the potential inconsistency with Beneficiary Identification Methodology, we propose to first obtain physician participation in the model, then utilize the CMS Form 2728 Medical Evidence Report required to be completed within 45 days of first beginning dialysis. We believe that most practicing nephrologists know which of their patients starting dialysis are Medicare beneficiaries within the first month of dialysis well before CMS does. Moreover, our model is intended to focus on this vulnerable time in patients' lives in such a way as to make their quality of care and cost of care better than currently exists. This culture change focus is not expected to be limited only to patients included in the model instead we anticipate a halo effect such that all patients who may face the development of end-stage kidney disease will be favorably impacted by changes in practice patterns.

In creating the proposed PFPM, RPA considered diligently how beneficiaries with Chronic Kidney Disease (CKD) might be included. Such a model was ultimately deemed not to fit with our goals to be simple and utilize existing fee structures as well as to benchmark for financial success. We respectfully disagree with the presumption that not aligning beneficiaries during CKD would prevent achieving the care goals identified once the patient enters our model. Every nephrologist is aware of the need to actively manage patients with CKD so as to orderly transition those patients progressing with their disease states to dialysis or transplantation and which, to date, is successfully accomplished far less than anyone desires. Additionally, as noted by Goyal and Weiner in a recently published editorial, "Preemptive transplant listing is one quantifiable marker of improved access to medical care before dialysis initiation, potentially

serving as a proxy for other valuable care before dialysis initiation, including management to slow kidney disease progression, discussions of kidney replacement therapy, and dialysis access planning and creation” (*Clin J Am Soc Nephrol* 13:982-983, 2018.doi:<https://doi.org/10.2215/CJN.06390518>).

RPA like HHS has considered the issue of perverse incentives in enrolling participants, either by what is known as “cherry-picking” or “lemon-dropping.” We believe that our model indirectly incentivizes the appropriate use of palliative care, currently under-utilized in CKD transitioning to dialysis. Although we would not agree with specifying a quantifiable level of residual renal function as a gating step to start dialysis (as the decision to initiate dialysis remains a clinical one), we would obtain that information via the CMS Form 2728 and monitor it to prevent unintended consequences. Moreover, we are not certain that patients on dialysis with some residual renal function would actually cost less, as it is recognized that hemodialysis hastens decline of existing residual renal function and some residual renal function on peritoneal dialysis is actually desirable.

Regarding care coordination with dialysis providers, it remains in the dialysis providers best interest to have patients orderly transitioned to dialysis, such that these patients would have less hospitalizations and less absences from dialysis units and better experiences as evidenced by quality of care metrics already in existence. This model does not restrict beneficiary choice, and as such, other healthcare providers will continue to participate in the beneficiary’s care. We do foresee, however, the potential for innovation in care determined locally with the hopes that the financial incentives for even a small population might foster creativity. Put another way, nephrology practices choosing to participate in the model should have the latitude to determine how care coordination should be optimized for their patient population and geography. Also, we would urge HHS/CMS to not allow the fact that some practices will make the appropriate decision for their circumstances not to participate eliminate the opportunity for other practices to attempt to improve care coordination and generate Medicare program savings by entering this model.

RPA acknowledges fully virtually all of the issues and concerns raised by PTAC and HHS, as they were first considered and discussed at length by us as part of our internal processes. These considerations notwithstanding, PTAC in December 2017 unanimously voted to recommend our proposed model to HHS for implementation. Recognizing that you at HHS have the final say, we nonetheless are hopeful that you would be able to utilize this proposal in creation of a workable and acceptable model in order to achieve the original intent of our organization in crafting this proposal.

As always, RPA welcomes the opportunity to work collaboratively with HHS/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 HHS/CMS in its future work on alternate payment models. 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 "Michael D. Shapiro". The signature is fluid and cursive, with the first name "Michael" and last name "Shapiro" being more legible than the middle initial "D".

Michael D. Shapiro, MD, MBA, FACP, CPE

RPA President