October 24, 2018

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
Attention: OIG–0803–N
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C 20201

RE: OIG–0803–N; Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti- Kickback Statute and Beneficiary Inducements CMP

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 the HHS OIG request for information (RFI) on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care, in the context of the anti-kickback statute (AKS).

RPA commends the Office of Inspector General (OIG) for identifying ways to promote care coordination and advance the delivery of value-based care by modifying or adding new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of 'remuneration', while being mindful of its duty to protect against harms caused by fraud and abuse.

RPA's comments address potential revisions in the AKS affecting the following areas:

- **Nutritional supplements provided to dialysis patients**
- **Provision of telehealth technologies to home dialysis patients resulting from the Bipartisan Budget Act**
- **Exceptions to the AKS pertaining to innovative revenue distribution models in Medicare Shared Savings Plans and other alterative payment models (APMs)**

Nutritional supplements provided to dialysis patients

Research indicates that poor nutritional status is extremely common in dialysis patients.[1] However, that subpar nutritional status can in many situations be addressed by providing dialysis patients with a relatively low-cost nutritional supplement regimen consisting of supplements such as Vitamins B, C, and D, as well as additional iron, calcium and oral protein supplements, tailored to specific patient need. Improved nutritional status can lead to lower mortality rates and improved patient well-being.

Despite the benefits attendant to provision of nutritional supplements to patients on dialysis, nephrologists and/or dialysis facilities currently are potentially are risk if they provide them to their patients since no safe harbor from the AKS for nutritional supplements is in place, and thus providing them could be considered a beneficiary inducement subject to a civil monetary penalty (CMP) or an AKS violation. Given the benefits of the supplements to a dialysis patient's nutritional status, **RPA strongly urges the OIG to create a safe harbor for nutritional supplements**, subject to the standard guardrails in place for existing safe harbors (that they not be offered as part of an advertisement or solicitation, that they be provided specifically for the patient's end-stage renal disease (ESRD) and that they meet all other regulatory requirements).

Provision of telehealth technologies to home dialysis patients resulting from the Bipartisan Budget Act

In the RFI, the OIG seeks input on how to structure a safe harbor or exception to the beneficiary inducement CMP necessitated by the enactment of that Bipartisan Budget Act (which included a provision that allows monthly dialysis services to be provided via telehealth), and how to define "telehealth technologies" for these purposes. Generally, RPA believes CMS should seek ways to provide as much flexibility as practicable to promote use of home dialysis modalities.

Specifically, and as noted in our comments on the 2019 Medicare Fee Schedule proposed rule, RPA believes that the OIG should take a broad view with regard to the allowable interactive telehealth technology platforms to be used from the patient's home. Allowing patients to use their mobile tablet or hand-held devices to interact with their nephrologist during the monthly face-to-face interactions occurring via telehealth would eliminate a major unnecessary regulatory barrier to the promotion of home dialysis. Additionally, if development of a waiver process is necessary to address confidentiality concerns as they relate to protected health information (PHI), RPA urges the Agency to create such a waiver addressing interactive technology used in the patient's home in underlying sub-regulatory guidance.

In summary, with regard to the home dialysis telehealth benefit enacted as part of the Bipartisan Budget Act, RPA believes that the OIG should:

[1] Oral Nutritional Supplement Use in Dialysis Patients: Full Speed Ahead?
Wright, Seth et al.
American Journal of Kidney Diseases, Volume 60 , Issue 4 , 507 - 509

(1) Allow patients to use their mobile tablet or hand-held devices to interact with their nephrologist during the monthly face-to-face interactions occurring via telehealth;

(2) Establish a waiver process to address confidentiality concerns as they relate to protected health information (PHI); and

Exceptions to the AKS pertaining to innovative revenue distribution models in Medicare Shared Savings Plans and other alterative payment models (APMs)

Another area where regulatory provisions may act as barriers to coordinated care and thus would benefit from the existence of a safe harbor pertains to the development of innovative revenue distribution models in Medicare Shared Savings Plans (MSSPs) and other alterative payment models (APMs). It is our understanding that in MSSPs and similar models CMS has established constraints on how the savings generated by these models can be shared with the nephrologists and other physicians that may limit how the overseeing entity can reward high performers. RPA believes that such limitations are antithetical to the goals of value-based care. **Therefore, RPA urges the OIG to develop a safe harbor that allows for the development of innovative revenue distribution models in Medicare-sponsored alternative payment models (APMs).**

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 to reduce unnecessary and inappropriate regulatory burdens affecting Medicare providers. 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,

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

RPA President