KIDNEY CARE PARTNERS

December 20, 2019

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Joanne M. Chiedi
Acting Inspector General
Office of the Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Re: OIG-0936-AA10-P: Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Secretary Azar and Acting Inspector General Chiedi:

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" proposed rule (Proposed Rule). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD). We appreciate the attempt to clarify the anti-kickback and civil monetary penalty rules before the new value-based models for ESRD are implemented. Knowing these rules before applying for a model is important. There were several dialysis facility providers that did not participate in the ESRD Seamless Care Organizations (ESCOs) because of concerns and questions about how waivers might or might not be provided. Knowing the rules in advance can eliminate this barrier and creates an environment in which facilities and nephrologists are more willing to take the risk and participate in innovative models.

We wish to reiterate our commitment to work with the Administration to help achieve its objectives. KCP is uniquely situated to assist, because our members cover all aspects of the kidney care community – patients and patient advocates; physicians, nurses, and other health care professionals; dialysis facilities of all types and sizes providing services across the United States; and manufacturers seeking to develop and support innovative treatment options for patients.

KCP is excited to support the Administration in its efforts to improve kidney care for all Americans. The proposals in this Proposed Rule along with those outlined in the "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" proposed rule would help eliminate some of the barriers to improving care coordination for patients living with kidney disease and kidney failure. We look forward to working with you to ensure these policies are finalized and applied to nephrologists and dialysis

facilities so that regulations support the delivery of value-based kidney care which is a central principal of the Administration's "Advancing American Kidney Health" initiative.

I. Why Care Coordination Is Essential to Improving Kidney Care In America

The goal of patient-centered care is to "improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure."[1] In "Advancing American Kidney Health," HHS describes its objective to create a "payment model to encourage more coordinated care to delay kidney failure and ensure that people living with kidney failure have access to the best available care options."[2]

KCP and its members, many of whom are participating in the ESCO model, strongly support care coordination efforts. We agree with MedPAC that this model "provide[s] a holistic approach to the care of beneficiaries with CKD, who often have multiple comorbidities in addition to kidney disease" and "hold[s] both dialysis facilities and managing clinicians jointly accountable for the outcomes…of beneficiaries with CKD, including rates of home dialysis and transplantation."[3] MedPAC also recognizes the need to include transplant centers when transplantation is incorporated into such models as well.[4]

Current laws create barriers to coordinated care and educational efforts for the ESRD populations. For example, while KCP agrees with the Administration's suggestions in the ESRD Treatment Choices (ETC) model that social workers and dieticians who work in facilities could assist nephrologists is improved educational efforts, under current law, such coordination is not permissible.

As CMS and the OIG have recognized, the current application of the Stark/anti-kickback laws remains a substantial barrier to coordinating care. These laws and their corresponding regulations prohibit physicians from referring patients for certain designated health services paid for by Medicare to any entity in which they have a "financial relationship." Yet, for nephrologists and facilities to work together to increase the number of patients who select home dialysis and the number of patients referred for transplant, such referrals from physicians to facilities should be occurring. Similarly, dialysis facilities that employ or contract with dieticians, social workers, and other health care professional should be allowed to coordinate with physicians, but again such activities are prohibited by current law.

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[1] HHS, "Advancing American Kidney Health" 4-5 (July 2019).
[2] *Id.* at 15.
[3] MedPAC, Letter to CMS Administrator Seema Verma (September 3, 2019).
[4] *Id.*

We understand that oversight agencies are hesitant to waive or offer protections from these restrictions, which were originally enacted to prevent fraud and abuse and protect the Medicare programs. However, many of these requirements were established decades ago in a more traditional fee-for-service environment and are not well suited for bundled payment systems or modern, coordinated care models. As such, protections from the Stark/anti-kickback laws are essential elements for any effort to bring greater coordinated care to Medicare. KCP and our members welcome the opportunity to work closely with the Department to help ensure that such waivers would be as narrow as possible to effectuate the goals of improved care coordination and value-based programs.

II. Comments specific to Proposed Rule Proposals

As a threshold matter, KCP applauds the Department and OIG for proposing safe harbor protections under the Federal anti- kickback statute for certain coordinated care and associated value-based arrangements between or among clinicians, providers, suppliers, and others. We also support protections under the anti-kickback statute and civil monetary penalty (CMP) law that prohibit inducements offered to patients for certain patient engagement and support arrangements to improve quality of care, health outcomes, and efficiency of care delivery that meet all safe harbor conditions, as well as the new safe harbor for donations of cybersecurity technology and amend the existing safe harbors for electronic health records (EHR) arrangements, warranties, local transportation, and personal services and management contracts. It is important that these protections apply to nephrologists and dialysis facilities as well to allow for care coordination for patients with kidney disease and kidney failure.

Our more detailed comments focus on the specific provisions related to the provision of dialysis.

A. CMP exemption for certain telehealth technologies offered to patients receiving in-home dialysis, also pursuant to the Budget Act of 2018.

KCP is pleased that the Proposed Rule provides an exemption to the CMPs to assist in the implementation of the Budget Act of 2018 that expanded the ability of beneficiaries on home dialysis to receive required monthly clinical assessments to monitor their condition using telehealth. The Congress sought to expand the number of originating sites from which the beneficiary can have a telehealth assessment with the nephrologist to include freestanding dialysis facilities and the patient's home and enables these telehealth visits to be conducted from the expanded list of sites without geographic restriction. The Proposed Rule's provisions, if finalized, are an important step to take to ensure that the provisions meet the Congressional goals.

KCP believes it is important to expand the number of individuals who can properly and effectively use home dialysis, particularly in rural and underserved areas. Home

dialysis requires a special commitment to care, and for those individuals with the capability and support necessary to dialyze at home, the ability to use technology to have a virtual visit with their physician can improve the quality of care and quality of life for ESRD beneficiaries.

The Budget Act of 2018's exception provides that protected items or services may not be offered as part of any advertisement or solicitation.[5] The second criterion included in the statutory exception requires the telehealth technologies to be provided for the purpose of furnishing telehealth services related to the individual's ESRD.[6] KCP supports with suggested modifications below the OIG proposal to interpret "for the purpose of furnishing telehealth services related to the individual's end stage renal disease" to mean:

> that the technology contributes substantially to the provision of telehealth services related to the individual's ESRD, is not of excessive value, and is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes.[7]

In response to the OIG's request for comments,[8] KCP believes that in the vast majority of the cases when a provider or facility provides hardware to a home dialysis patient, the period of use by the patient would most likely render the ownership interest obsolete because its useful life will expire first. However, we do request that the OIG leave available the possibility of retaining ownership, especially in situations when a beneficiary tries home dialysis, but because of clinical or social reasons (such as the loss of a caregiver), decides not to remain on home dialysis. In such situations, the provider or facility should be allowed to take ownership of the hardware so that it could be used with another patient seeking to use telehealth to allow him/her to rely upon telehealth when selecting home dialysis. This policy would also create a guardrail that would reduce the risk of the equipment being used primarily for non-home dialysis reasons.

Also in response to the OIG's request for comment, KCP encourages the OIG not to interpret the phrase "for the purpose of furnishing telehealth services related to the individual's end stage renal disease" [9] in a manner that is more restrictive than the statute. Patients who rely upon technology for telehealth need to be comfortable and familiar with the equipment. Limiting the telehealth technology to products that have "no more than a de minimis benefit for any purpose other than furnishing telehealth services related to the individual's ESRD" [10] would eliminate the use of home computers, tablets, and smart

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[5]Proposed Rule Display Copy at 319.
[6]*Id.* at 320.
[7]*Id.* at 320-21.
[8]*Id.*
[9]*Id.* at 321.
[10]*Id*.

phones, which are the very items that patients may want to use to create a seamless experience.

We understand the concern that allowing such devices to be provided to patients when they have non-health care functions could be considered an inducement. However, patients who receive such devices would have to not only accept them, but accept the obligations and responsibilities of home dialysis. The nature of the decision to dialyze at home should act as an appropriate standard or guardrail to ensure the appropriate use of such devices. If anything, the OIG may wish to require patients who receive such products to return them to the provider or facility if they decide to return to an in-center dialysis setting or if they receive a transplant.

KCP recommends that the OIG provide more flexibility and not limit its interpretation of "telehealth services related to the individual's end stage renal disease" to mean only those telehealth services paid for by Medicare Part B.[11] Care coordination, by definition, requires providers across the Medicare silos to provide care. Limiting the telehealth services only to Part B will create an unnecessary barrier to achieving the Administration's goal of comprehensive care coordination for the dialysis population. In addition, the technology should be able to assist patients with all related medical needs – not only the patient's ESRD Part B services. Dialysis patients have multiple comorbidities that may or may not be related to their ESRD. To allow for care coordination and comprehensive care management, the use of the equipment should not be limited only to ESRD. The equipment should be available to assist with preventing complications and further progression of kidney disease and a patient's other comorbidities. In addition, the equipment should be available for patient education services and other services, such as diet counseling. It should also be allowed to collect patients vital signs and other information for any of the health care providers' participating with the patient in telehealth. Therefore, we ask that the OIG remove the language "paid for by Medicare Part B" and rely upon the construction written in the statute.

KCP also supports many of the OIG's proposed conditions for the telehealth exception, which the suggested refinements and some exceptions noted below.

- KCP agrees that a person should not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the item or service as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals.[12]

[11] *Id.*
[12] *Id.* at 322.

- KCP asks that the OIG not limit the policy by including the term "interactive telecommunications systems," which is currently defined as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system."[13] Telephones, facsimile machines, and electronic mail systems should not be excluded, because it should be permissible to divide the audio and visual components across two different types of equipment. Monitoring equipment that can report patient data to physicians and facilities, such as Bluetooth enabled stethoscopes and thermometers, would not meet the "interactive" definition, yet are critically important to providing effective telehealth services. In addition, the technology for telehealth may also be needed to store or forward information. Limiting it to "interactive" only products unnecessarily limits the scope of the benefit that will create an unnecessary barrier for patients and providers.

- KCP interprets the proposal that providers and dialysis facilities should be required to provide the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients satisfying specified, uniform criteria,[14] as seeking to ensure that all qualified patients have the potential to access such services. However, as written, the broad language does not allow physicians or facilities to ensure that patients who receive such equipment are likely to benefit from it. Telehealth technologies are expensive and providers should have the flexibility to allocate these limited resources in ways that tailor the services to patients most likely to benefit from them.

- KCP also supports the condition that a provider or facility should be allowed to furnish telehealth technologies under the safe harbor only after making a good faith determination that the individual to whom the technology is furnished does not already have the necessary telehealth technology, and that such technology is necessary for the telehealth services provided.[15]

- KCP also believes that patient choices and autonomy are critical principals that need to be supported under the Proposed Rule. We do not oppose making sure that patients understand that when they receive such technology that they retain the freedom to choose any provider or supplier of dialysis services and to receive dialysis in any appropriate setting. However, this requirement would

[13] *Id.* at 323-24.
[14] *Id.* at 326.
[15] *Id.* at 327.

> duplicate existing requirements in the ESRD Conditions for Coverage, so does not seem necessary.[16]

KCP does not believe it is necessary or adds sufficient value that outweighs the burden of the proposed rule to require providers or facilities to provide a written explanation of the reason for the technology and any potential "hidden" costs associated with the telehealth services to any patient who elects to receive telehealth technology.[17]

We also support the proposal that would condition safe harbor protection on the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration.

Finally, KCP supports the proposal not to include a materials and records or other documentation requirement.[18] This proposal is important to reduce unnecessary administrative burden on both providers and facilities.

B. Dialysis Community Concerns

KCP understands the unique attributes of the dialysis community and the business arrangements that have developed over the years in this Medicare-dominated area of health care (more than 80 percent dialysis patients depend on Medicare). Chronic underfunding in the Medicare program has driven consolidation as the need for efficiencies drove business operations. Data from the U.S. Renal Data System (USRDS), the ESRD Quality Incentive Program, and industry supported initiatives show that concerns about quality are misplaced. Quality has been steadily improving during the past twenty years, but the relatively flat ESRD PPS rate has meant that quality has hit a plateau. The fraud and abuse laws, which have created barriers to care coordination, have also blocked additional improvement.

Within the confines of the current PPS that actively discourages or prohibits care coordination, dialysis facilities have improved the quality of care patients have received during the last ten years, according to MedPAC. Moreover, unless the barriers to care coordination are eliminated and nephrologists and facilities are allowed to interact the way others in the health care community can, patient quality of care will stagnate and the Medicare program expenditures will continue to rise for a patient population. The ESCO clearly established that cost savings can be achieved while quality of care improves over current levels, but these goals cannot be achieved without appropriate waivers and/or protections that allow for care coordination to occur across the various providers involved in the care of each kidney disease patient.

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[16] *Id.* at 328.
[17] *Id.* at 327-28.
[18] *Id.* at 329.

KCP urges the OIG not to create barriers to care coordination for dialysis patients by adding requirements under the Care Coordination Safe Harbor for dialysis providers. The existing safeguards applicable to other providers would be equally effective in terms of dialysis providers. Given the eagerness of the community to embrace the ESCOs and the very public interest in establishing the next generation of payment models, we do not believe that allowing coordination will lead to additional concentration of the market. However, not allowing such coordination will stifle patient care, further reducing the number of organizations able to survive in a failed market. The exclusions and protections outlined in the Proposed Rule would not support pay-for-referral schemes. However, KCP would welcome the opportunity to work with the OIG to identify potential monitoring or reporting requirements that could alleviate any concerns, including fair market value requirements and restrictions that prohibit paying remuneration based on the volume or value of referrals.[19]

III. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. We reiterate our willingness to work with the OIG and the Department to ensure that the anti-kickback and CPMs do not create unnecessary barriers to coordinating care for dialysis patients and those living with earlier stages of kidney disease. Please do not hesitate to contact Kathy Lester at klester@lesterhealthlaw.com or 202-534-1773 if you have any questions or would like to discussion our comments.

Sincerely,

John Butler
Chairman

[19]See *id.* at 109-110.

Appendix A: Kidney Care Partner Members

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