December 20, 2019

The Honorable Alex M. Azar	The Honorable Seema Verma
Secretary	Administrator
Department of Health and Human Services	Centers for Medicare & Medicaid Service
200 Independence Avenue, SW	200 Independence Avenue, SW
Washington, DC 20201	Washington, DC 20201

Dear Secretary Azar and Administrator Verma:

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" (Proposed Rule). We applaud the Department of Health and Human Services (HHS) for initiating the "Regulatory Sprint to Coordinated Care" (Regulatory Sprint). 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 effort to remove barriers in the Stark laws that inadvertently make it more difficult, and in some instances, impossible, to coordinate care for patients. Many KCP members faced this difficult situation when they sought to participate in innovative care models, such as the Comprehensive ESRD Care (CEC) Model. Because of uncertainties about how the barriers created by the Stark laws would be addressed, several organizations decided not to participate. Knowing the rules in advance would eliminate one of the barriers and create 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 to improve the lives of kidney care patients. 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 and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules regarding Beneficiary Inducements" proposed rule would help eliminate several 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 that 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, some of whom are participating in the CEC 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 with improving 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 remain 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 efforts to bring greater coordinated care to Medicare. KCP and our members welcome the opportunity to work closely with the Department and CMS 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 CMS for proposing to create new exceptions to the physician self-referral laws for certain value-based compensation arrangements between or among physicians, providers, and suppliers. With the specific recommendations below, we also support the new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician, as well as the new exception for donations of cybersecurity technology and related services and modifications to the existing exception for electronic health records (EHR) items and services. Our comments offer small, but critically important, tweaks to the proposals to ensure that the exceptions address practical issues in these areas as well. We would like to continue working with CMS to help achieve the goal of "alleviat[ing] the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties."[5]

A. Facilitating the Transition to Value-Based Care and Fostering Care Coordination

KCP supports the new exceptions to the physician self-referral law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise (VBE) of which they are participants. We agree that the exceptions should apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.[6]

The Medicare ESRD program was the first Medicare program to incorporate value-based purchasing. KCP strongly supports this program, known as the ESRD Quality

[5] Proposed Rule Display Copy at 27.
[6] *Id.* at 30-31.

Incentive Program (QIP), as well as a community-driven measure development organization known as the Kidney Care Quality Alliance (KCQA) that develops, seeks NQF endorsed for, and maintains meaningful measures. KCP and its members also have worked closely with CMS and the Congress during the last several years to test alternative payment models that would eliminate the silo approach to health care that can have such a negative impact on patient care and outcomes. Thus, we believe the VBE exception is an important next step in expanding beyond the work already done. Without it, the Stark laws would prohibit the very activities and interactions between dialysis facilities, nephrologists, and other health care providers needed to truly effectuate care coordination and pay for patient outcomes (value) rather than the volume of services provided.

In this spirit, we offer the following suggested modifications to the definitions.

- KCP has consistently advocated for patient-center measures. We support the definition of value-based entities including <u>improving</u> quality of care, but also ask the definition include <u>maintaining</u> the quality improvements, which is important to ensure care continuity. In addition, we would appreciate it if CMS could provide examples of improving quality of care. We support including clinical measures, but also suggest adding quality of life, patient-reported outcomes, and prescription adherence measures.

- KCP also believes it is important to coordinate care as early as possible after the diagnosis of kidney disease. Thus, we ask that CMS clarify in the definition of target patient population that it includes not only patients diagnosed with ESRD, but also patients with CKD. As the Innovative Center recognizes, early intervention is essential to improving patient outcomes and slowing the progression of the disease.

- KCP agrees that evidence based medicine is important, but we also ask that CMS provide flexibility to allow for treatment options that may not have been the subject of randomized controlled trials. We know that in the area of kidney care in particular there are many standards of care and innovative practices that while effective have not been the subject of randomized controlled trials. Thus, we ask that CMS not impose a restriction that would eliminate the use of such care options.

B. Meaningful Downside Financial Risk Exception

CMS proposes to protect remuneration (for, or resulting from, value-based activities undertaken by the recipient) paid under a value-based arrangement when the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value- based enterprise, which KCP generally supports. The agency also seeks comments on how to define "meaningful downside financial risk," which it proposes to

mean "that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement."[7] KCP agrees that it is important to protect renumeration paid under a value-based arrangement when a physician has meaningful downside risk, but asks that CMS also include shared savings options, as well as losses, in the definition to be consistent with the overall approach to many value based arrangements.

C. The Volume or Value Standard or Other Business Generated Standard

KCP support the objective test for evaluating whether compensation takes into account the volume or value of referrals or business generated by a physician. It is important that any such standard be predictable and straightforward to implement. Subjective or confusing policies would create unnecessary barriers to participation, as the kidney care community experienced when the CEC models were unable to provide the waivers to the fraud and abuse laws upfront. Many providers felt they could not take the risk. Therefore, we support CMS using the objective test in this instance.

D. Definition of Designated Health Services (DHS)

KCP supports the proposed refinements to definition of DHS, but asks that CMS apply it not only to hospitals, but also to other providers. The same rationale that applies to excluding the furnishing of services when they do not affect the amount of Medicare's payment to the hospital is also applicable to dialysis facilities, nephrologists, and other health care providers in the context of providing kidney care.

E. Removing Barriers to Data Sharing

During the past 15 years, KCP has been a strong advocate for improving data sharing to improve patient outcomes. Our members have worked with other health care providers to obtain medical records and other information about the care patients receive in other settings so that their treatments in dialysis facilities or by nephrologists can take such care into account. Unfortunately, we have not been able to fully achieve our goal of true data sharing and care coordination.

Thus, we are pleased that CMS has identified data sharing as an area for an exception. It would be helpful if CMS could provide clarification in the final rule that providing remote access to health information on patients cared for by multiple care teams does not constitute remuneration. Patients with kidney disease often have multiple care providers, including dialysis facilities, nephrologists, hospitals, nutritionists, and other specialists. Excluding data sharing from the definition of renumeration would be an

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[7] *Id.* at 65-66.

important step to breaking down the barriers these providers face when trying to share patient data.

We also ask that CMS exclude from the definition of renumeration any expenses incurred for data sharing when those costs are related to complying with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's definitions of treatment, payment, and health care operations, as well activities to comply with Medicare participation or reimbursement requirements.

III. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. We reiterate our willingness to work with the CMS and the Department to ensure that the Stark laws 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

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
National Kidney Foundation
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care