KIDNEY CARE PARTNERS

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1717-P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: CMS-1717-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage ; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Dear Administrator Verma:

Kidney Care Partners (KCP) would like to reiterate our support and appreciation of the Administration's focus on patients living with chronic kidney disease (CKD) and kidney failure. The Medicare program, itself, has a unique role. Because the Congress extended Medicare coverage for all Americans living with kidney failure, known as End-Stage Renal Disease (ESRD), by granting them eligibility to enroll in Medicare based on their disease status and not their age, Medicare policy essentially drives the care and treatment options available for these patients. The President recently identified three primary objectives of his "Advancing American Kidney Health" initiative to improve the lives of patients living with kidney disease: (1) increasing efforts to prevent, detect, and slow the progression of kidney disease; (2) providing patients who have kidney disease with more options for treatment; and (3) increasing the availability of organs for transplant.[1] The KCP supports these goals.

We are writing today to offer comments on the provisions of the Hospital Outpatient Prospective Payment System proposed rule (Proposed Rule) that pertain to the Organ Procurement Organizations (OPOs) and the transplant centers. We are pleased that CMS is considering a comprehensive proposal that would update the OPO Conditions for Coverage

[1]HHS, "Advancing American Kidney Health" (July 2019).

(CfCs) and potentially update the transplant center Conditions of Participation (CoPs). As described below, KCP encourages CMS to update the CfCs and CoPs in ways that will reduce the discard rate of kidneys and require alignment around transplant center waitlist criteria. The KCP would welcome the opportunity to work with the Administration, OPOs, and transplant centers to develop appropriate policies across the kidney care community to improve access to transplant for patients living with kidney disease.

KCP agrees that the best option for many patients living with kidney failure is a kidney transplant. KCP members have asked CMS to improve the allocation of organs and eliminate barriers that may result in organs being discarded. We support the Department's objectives to: (1) "[i]ncrease the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate"[2]; and (2) "[i]ncrease the number of living donors by removing disincentives to donation and ensuring appropriate financial support."[3] We are also encouraged by the steps HHS plans to take to achieve these objectives and that it has outlined in that document that seek to remove requirements that may create an incentive to discard organs unnecessarily.

- "HHS is updating the PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. The goal of the existing 2013 Guideline was to reduce risk of unintended HIV, HBV, and HCV transmission, while preserving availability of high quality organs."

- "HRSA has funded the OPTN to expand the COIIN pilot project in 2020, allowing more kidney transplant programs to participate in this OPTN quality improvement activity focused on changing program waitlist management and organ acceptance practices."

- "The Innovation Center's ETC Model includes a learning collaborative operated by the Center for Clinical Standards and Quality (CCSQ), designed in collaboration with HRSA and informed by the HRSA OPTN COIIN, to reduce the disparity in performance among Organ Procurement Organizations (OPOs) and transplant centers with the goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers."

- "HRSA, through the OPTN, is developing a new model to test accelerated placement of certain kidneys that are at high risk for discard."

- "Per the 2019 OMB regulatory agenda, CMS is reviewing the OPO conditions for coverage and will be proposing changes to the standards used to evaluate OPOs to

[2] *Id.*
[3] *Id.* at 19.

> ensure proper data collection on the availability of transplantable organs and transplants."[4]

We support these policy steps and believe they are critical to achieving the Department's overall objective. Thus, we encourage CMS to incorporate these policies into the OPO CfCs or implement them through other policy mechanisms as soon as possible.

In addition to addressing the limited supply of organs, KCP also emphasizes that it is important to eliminate the barriers created by the fact that each transplant center has its own waitlist criteria that patients must navigate. A good example of this problem has been summarized by IPRO, the ESRD Network for the South Atlantic. In a document prepared to help patients navigate the transplant process, it provides the following advice.

> A kidney transplant is a possible treatment option for people on dialysis. However, not everyone who wants a transplant can be considered eligible to receive one. Only transplant center professionals can determine if a patient is a good candidate for a transplant.
>
> Each transplant center uses its own set of standards for deciding if a patient is a good candidate for a kidney transplant. In some cases, a patient can be turned down by one transplant center, but found to be eligible at another transplant center.
>
> The table on the following pages is a tool to help guide dialysis patients, their family members and care partners to the transplant centers that could most likely meet their needs.[5]

Moreover, of the nine transplant centers in Georgia, South Carolina, and North Carolina, none has the same "absolute transplantation criteria." Standardized transplant center waitlist criteria are necessary to level the playing field for patients, nephrologists, and facilities and to prevent cherry picking by transplant centers. To see the differences among transplant center criteria in just one area of the country, please review Appendix A.

To address this problem, KCP asks that CMS through the transplant center CoPs, or other policy mechanisms, standardize transplant waitlist criteria. In addition, transplant centers should be required to clearly and publicly state their criteria for waitlisting patients. Currently, there is no source for this information.

In conclusion, we thank you for providing KCP with the opportunity to provide suggestions on how to improve access to transplant in the United States. We reiterate our commitment to working with the Administration to eliminate barriers to transplant. Please do

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[4] *Id.* at 18-19.

[5] IPRO, "South Atlantic Area Kidney Transplant Center Referral Guide" (on file with author; available upon request).

not hesitate to contact us through our counsel in DC, Kathy Lester (klester@lesterhealthlaw.com) if you have any questions or would like to discuss these ideas with us in more detail.

Sincerely,

Allen Nissenson
Chairman
Kidney Care Partners

Appendix A: IPRO Referral Guide Summary Chart

ABSOLUTE EXCLUSION CRITERIA	GEORGIA		
	Augusta University Medical Center Transplant Program	Emory Transplant Center	Piedmont Hospital Transplant Institute
Active or untreatable infection	✘	✘	
Malignancy or history of cancer		✘– Active Malignancy Only	
Body Mass Index - kg/m² (BMI)	>42	>45	>45
Age	>80		
Myocardial infarction or active myocardial ischemia			
Advanced Coronary Artery Disease (CAD)	✘	✘	✘
Cerebrovascular accident within the last 3 months			
Severe peripheral vascular disease		✘	
Advanced chronic obstructive pulmonary disease (COPD)	✘	✘	✘
Incomplete immunization series			
Active Tuberculosis (TB)		✘	
Cirrhosis / Liver Disease / Oxalosis	✘		
Liver biopsy with stage ≥3 fibrosis			
Current Positive T cell Crossmatch			
Sickle Cell Disease			
Good Pasture's Syndrome			
Wagener's Granulomatosis			
Active Systemic Lupus Erythematosus			
Active Vasculitis / Glomerulonephritis			
Psychiatric illness not controlled with medication	✘	✘	✘
Lack of social support for financial resources	✘	✘	✘
Non-Compliance with Medical Regimen	✘	✘	
Active smoker			
Active substance abuse (drug or alcohol)	✘	✘	✘
Miscellaneous	Yes self referral	Yes self referral	Yes self referral

Absolute Exclusion Criteria: A list of medical conditions that would prevent a person from being eligible for a transplant. (Every transplant unit has its own set of exclusions.)

	NO. CAROLINA					SO. CAROLINA
	Carolinas Medical Center Renal Transplant Program	Duke University Hospital Transplant	UNC Hospital Transplant Program	Vidant Medical Center	Wake Forest Baptist Hospital Medical Center	Medical University of South Carolina Transplant Center
	✘			✘	✘	✘
	✘– Active Malignancy Only				✘– Active Malignancy Only	✘
	>40	>40	>40	>42	>45	>40
			>80		>85	
	Within 6 mo's.	Within 6 mo's.				
	✘		✘			✘
	✘					
	✘					
	✘	✘– Only if severe	✘	✘– Only if severe	✘– Only if severe	✘
	✘					
	✘		✘			
	✘				✘	
	✘					
	✘					✘
						✘
						✘
						✘
	✘					✘
	✘	✘		✘	✘	✘
	✘	✘		✘	✘	
	✘	✘		✘	✘	✘
			✘			
	✘	✘	✘	✘	✘	✘
	No self referral	Yes self referral and Chronic SNF	Yes self referral	Yes self referral	Yes self referral	Yes self referral

Appendix B: 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
Braun
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
Dialysis Clinics, Inc.
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Renal Administrators Association
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care