KIDNEY CARE PARTNERS

February 11, 2021

The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

ATTN: CMS–3380–F2: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date

Dear Acting Secretary Cochran and Acting Administrator Richter,

On behalf of Kidney Care Partners (KCP), I am writing in support of the "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" Final Rule (Final Rule). Improving the availability of and access to solid organs, especially kidneys, is a priority for KCP and our members. We believe that the Final Rule with some small modification is a step in the right direction.

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 chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

Specifically, KCP agrees that it is important to strengthen the performance of the Organ Procurement Organizations (OPOs), which play such a vital role in providing patients who need a life-saving transplant with access to one. With just over 21,000 kidney transplant performed in 2018[1] and nearly 95,000 patients on current waitlists,[2] nephrologists and facilities face substantial limits in what they can do to increase the number of kidney transplants. Everyone agrees that we need more coordinated effort that focuses on OPOs, living donors, and transplant center criteria and polices is needed to improve access to transplant, especially for patients living with kidney failure. Thus, in addition to our support and recommendations related to the Proposed Rule, KCP has included suggestions related to engaging transplant centers more directly as well.

[1]UNOS Biweekly Update (January 10, 2020).
[2]National Kidney Foundation, "organ Donation and Transplantation Statistics" *available at* https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats.

I. KCP supports the proposed changes to the OPO measures.

As our history and support of value-based purchasing demonstrates, KCP understands and strongly believes in the power of performance measures to drive improved performance and accountability. Therefore, we support the revisions of the OPO measures and encourage CMS to finalize the new proposed donation rate of eligible donors and transplantation measures and the organ transplant rate measure outlined in the Proposed Rule.

We would like to provide two comments as it relates to the metric of the denominator. First, KCP supports using the inclusionary CALC metric was described in the Proposed Rule, as opposed to the denominator that used exclusionary diagnosis. Although CMS has shown that the net result in terms of among-OPO comparisons is similar, the CALC metric has superior face validity, because it restricts the denominator to inpatient deaths from causes that are consistent with donation, rather than the exclusionary measure which includes causes that never lead to donation. Second, agree that there should not be a risk adjustment.

KCP remains committed to working with CMS and the transplant community to ensure that the measures account for organs that are not appropriate to use for transplant. Such decisions and the criteria used to make them should be transparent and available publicly to promote accountability as well.

KCP also supports redefining the definition of success and basing on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with the top 25 percent of donation and transplantation rates for all OPOs. We also support the proposal re-certify an OPO if its performance based on these measures is not significantly different than the top 25 percent of high performing OPOs. We also encourage CMS to monitor the use of this standard closely.

We encourage CMS to closely monitor the impact of this standard as well. We believe it is important to hold OPOs accountable, but the standards also need to be practical and implemented in a way that provides continued patient access to transplantation as described later in this letter.

However, as described below, it is important that at the same time that OPOs are held accountable for transplantation rates, transplant centers must also be required to take steps that will reduce barriers created by inconsistent wait-listing criteria and practices related to rejecting organs that will also have a significant impact on the transplant rate as well. The accountability of transplant centers needs to be addressed simultaneously.

II. KCP supports revising the OPO decertification and recertification processes.

As noted in Section I, KCP supports holding OPOs accountable and any OPO that does not perform adequately, but we also want to make sure that the Department minimizes any potential disruptions when an OPO is decertified. We support opening service areas in such instances to competition and the criteria that the competing OPO must show that it is performing significantly better than the decertified OPO. We also believe that it is important to have an annual review of OPOs and for CMS to be able to decertify an OPO that is not performing adequately. It is important that throughout this process, CMS not allow there to be a lapse in any service area that would leave a gap in the collection and provision of organs.

KCP also supports the outcome measures assessment occurring at least every year and be based on data from the most recent 12 months of data. OPOs that are flagged as having donation rates or organ transplantation rates that are statistically significantly less than the threshold rates established by the top 25 percent of OPOs should be expected to take actions to improve their performance and include the specific actions that they will undertake to improve their outcome measures in their Quality Assessment and Performance Improvement (QAPI) program. We believe that the current four year cycle is too long a period for an OPO to be allowed to under-perform. We also want to make sure that the focus remains on improving outcomes and is more than simply an updating of the QAPIs. We appreciate that certain stakeholders have an interest in using data from death certificates, but we encourage CMS not delay implementation of the metrics it has proposed and which KCP supports even if it is considering other sources as of data.

III. KCP supports CMS collecting and making public OPO outcome measures of organ transplantation rates by type of organ.

KCP also supports reporting outcome measures of organ transplant rates by type of organ. The criteria qualifying for a transplant not only differ based on transplant center, but also on the type of organ. For example, patients who need hearts and livers must meet different criteria related to their health status than patients with Stage V CKD/ESRD. Transplant centers often require kidney transplant patient to be healthy (but for their kidney disease/kidney failure) in order to be placed on the transplant list. Some patients may even seek a pre-emptive transplant before their kidneys fail. Thus, it is important to see the difference in rates by organ type as well.

In reporting these data, we suggest that CMS consider how to distinguish the rate of organs used versus those that were expected to be used by organ type as well. This ratio would likely differ based on type of procurement, such as chest and abdomen procurement; how the donor management occurred (can affect usability of lungs and hearts); and other factors.

Understanding these data points by organ type would be very helpful in terms of trying to improving access to transplant generally, but especially to kidney transplants. We also encourage CMS to establish categories for multiple organ transplants, such as reporting pancreas-kidney transplants and similar common grouping of organs.

IV. The Department and CMS should also work with the kidney care community and other transplant experts to develop appropriate ways to address inconsistent transplant center waitlist criteria and make the transplant process more patient-centered, transparent, and easier for patients to navigate.

As we have noted, the Final Rule is an important step in the right direction to help increase the accountability of OPOs; however, we strongly encourage the Department and Agency to include transplants centers in its work to expand access to transplant as well. MedPAC also recognizes the need to include transplant centers in efforts to address kidney care more holistically.

Transplant centers play a critically important role in determining which patients get access to a transplant through the use of transplant waitlist criteria. Each transplant center has its own criteria that patients must navigate in order to be placed on the waitlist and be accepted as a candidate for transplant. (An example of the differences among transplant center criteria in one areas of the country is shown in Appendix A). KCP recognizes that some criteria differences are clinically appropriate. For example, some criteria highlight the unique expertise of a particular transplant center, such as being able to address the needs of HIV+ and/or sensitized patients. However, patient and provider organizations have also raised concern that other criteria may select for only the healthiest, most financially secure patients. Some centers, for example, refuse to waitlist patients who do not have a care-partner who can drive them to and from the transplant center for their follow-up visits. Others centers have financial criteria that patients must meet, which seem to weed out patients with lower socio-economic status. As a result of these inconsistencies, patients are needlessly being denied access to life-saving transplant.

Having a national dialogue to distinguish among criteria that are clinically appropriate versus those that are not would be helpful, especially if CMS plans to hold other entities accountable for transplant rates or having patients accepted on waitlists. These criteria determine which patients not only get on the waitlist, but also which patients are ultimately transplanted. KCP believes it is important to evaluate the criteria and, in consultation with kidney care and transplant experts, try to bring more consistency to transplant center criteria, while also recognizing the unique and valid differences among transplant centers to preserve and recognize important areas of specialization. We do not want the process to turn into a race to the bottom. These standards should also be clear

and easily accessible by patients, care-partners, and other health care providers to promote understanding and transparency. Part of this discussion should also focus on ways to ensure that transplant centers that work with high-risk patients are not penalized for doing so.

In addition, patients also have difficulty navigating these various criteria. Therefore, we encourage the Department and CMS to work with the kidney care and transplant communities to identify ways to make it easier for patients to navigate the transplant process.

In making these suggestions, KCP also wants to reiterate the importance of patient-centered decision-making that promotes patients and their physicians working together to determine whether a transplant is the right option for that individual patient. Transplant criteria should not interfere with that ultimate decision-making process.

KCP believes it is crucial that all participants in the kidney care and transplant communities work together to expand access to transplant in a manner that is patient centered. Only if all of the parties work together and agree to be held to accountable will we as a kidney care and transplant community be able to realize the goal of getting more patients to transplant.

V. Conclusion

Thank you again for providing us with the opportunity to comment. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester at 202-534-1773 or klester@lesterhealthlaw.com, if you have questions or would like to discuss our comments.

Sincerely,

John Butler
Chairman

Appendix A: IPRO Referral Guide Summary Chart

	GEORGIA		
ABSOLUTE EXCLUSION CRITERIA	**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