July 9, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244

Re: Increasing Organ Transplant Access (IOTA) Model

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure,

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule regarding its effect on those living with end-stage renal disease (ESRD).

C-TAC is a national non-partisan, not-for-profit coalition dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high-quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC comprises more than 200 national and regional organizations, including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

C-TAC defines serious illness as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their family caregivers. This definition has been widely adopted, including by the National Committee for Quality Assurance (NCQA) and the National Quality Forum (NQF). ESRD certainly qualifies as a serious illness using this definition.

Serious illness and, as the proposed rule notes, ESRD is also a health equity issue. A history of disenfranchisement has led to healthcare gaps across the country. Per a 2021 Commonwealth report on racial and ethnic health equity, communities of color live fewer years, on average, than white people do, are more likely to die from treatable conditions, and are also at higher risk for many chronic health conditions. For serious illness, the lack of access to health insurance and primary care mean many are diagnosed only at a late or end stage of illness, when disease-modifying treatment is typically no longer effective. Those from historically under-resourced

communities who also have serious illness experience poorer care and access, making improving their care a health equity opportunity.

Our overall comments on this rule are that we support the model and additional resources to help those with ESRD who want to pursue transplantation to assist them in that process. We share the agency's concerns that people of color or from low socioeconomic areas may have limited access to kidney transplantation and therefore support the aspects in this proposed rule that seek to address that inequality.

We also support the parts of the rule that will promote the concept of being a kidney donor to communities that have historically been under-represented with donor candidates. These communities need to be provided with clear and compelling reasons for why kidney donation is a meaningful and necessary thing to do.

Finally, we recommend that the following practices be added to the IOTA model:

- Advance care planning (ACP): ACP is a nuanced process through which patients identify their goals and consider their preferences for medical care over time. A recent randomized clinical trial published in JAMA found that ACP implemented by health care workers at dialysis centers improved preparation for end-of-life decision-making. It should therefore be required in the IOTA model, and all Medicare programs, as a way to ensure that the care being delivered is the care that the person wants. There is also evidence that people on dialysis have unrealistic prognostic expectations suggesting that they were not fully informed when making treatment decisions about hemodialysis, so it is critical that this be a component of the IOTA model. Finally, evidence also shows disparities in advance care planning among minority groups, so promoting it could help reduce inequity.
- Palliative care- People with ESRD would benefit from the inclusion of palliative care services in their care. This option should be included in the IOTA model and participants given the choice to add these supportive services to their care. By palliative care, we mean it's earlier inclusion in care per the CMS definition of *Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice".* We would also note that in CMCS's recent approval of adding palliative care services to the Hawaii Medicaid program, palliative care is redefined as a preventive service. This makes it even more appropriate for those in the IOTA model.

- Hospice- Although the goal of the IOTA model is to improve health and quality of life, some patients may not qualify for transplantation and therefore, the transition to hospice should be promoted when appropriate. Also, those who do receive a kidney transplant who subsequently have that transplant fail or develop other life-threatening complications should be assisted in pursuing hospice. We therefore suggest that the current transplant conditions of participation that require transplant centers to report their one year mortality allow those transplant patients choosing hospice to be excluded

from this measure. It is cruel to make people wait until a year after transplant to officially shift to end-of-life care so that the transplant center's measures look better and we are aware of numerous patient situations where this has unfortunately been the case.

Here are our comments on the Requests for Information (RFI) on Topics Relevant to the IOTA Model regarding Outcome Performance Measures:

- We support measures in the PRO-PM area as patient self-report is the gold standard to assess care quality. We therefore recommend consideration of the 2024 MIPS Measure #495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood and the Ambulatory Palliative Care Patients' Experience of Receiving Desired Help for Pain. Both are appropriate for people in the transplant process and involved in the IOTA model to get direct patient self-report on these important aspects of care.

Beyond PRO-PM, we suggest considering the following additional measures for the IOTA model per our comments earlier:

- Advance care planning (ACP): Building on our earlier mention of ACP, there is a HEDIS measure, a MIPS clinical quality measure, and CPT billing codes to cover this service. This measure should therefore be included in those for the IOTA model as a way to ensure that the care being delivered is the care that the person wants.

- Palliative care access and utilization- We suggest consideration of a measure in the IOTA on referral or access to palliative care so as to track how many of those in the model are also utilizing these important services.

- Timely and appropriate referral to hospice- We suggest a measure to ensure that a hospice referral is considered in appropriate cases and that the patient's eligibility for hospice is assessed and hospice offered. A claims-based outcome measure could capture the percent of model participants that transition to hospice and of those hospice patients, whether referral to hospice was timely based on hospice length of stay, i.e., less than seven days, etc.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Marian Grant, Senior Regulatory Advisor, C-TAC, at mgrant@thectac.org.

Sincerely,

Marian Grant

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