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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: Transmittal #R189SOMA New to State Operations Manual (SOM), Appendix X, Survey Protocol and Interpretive Guidelines for Organ Transplant Programs

The National Kidney Foundation has recently become aware of changes to the Centers for Medicare & Medicaid Services (CMS) interpretive guidance of the Conditions of Participation for Transplant Program that were finalized on May 24, 2019. This new guidance appears to be the first finalized change since guidance was issued in 2008. We are concerned with two of the changes affecting Living Organ Donation: 1) Tag X121 §482.98(d) *Standard: Independent Living Donor Advocate or Living Donor Advocate Team* and 2) Tag X 122 §482.98(d)(1) *The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis*. Both changes in the interpretive guidance have the unintended consequence of creating a barrier for willing living organ donors. The National Kidney Foundation is committed to protecting potential living organ donors and to removing barriers for living organ donors.

The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). We offer the following comments and recommendations to protect organ transplant recipients' access to medication.

Tag X121: §482.98(d) Standard: Independent Living Donor Advocate or Living Donor Advocate Team

The change in this guidance creates a new requirement that a potential living organ donor be assigned an advocate and have an interview with an advocate before evaluation. CMS defines the evaluation phase for living donor as, "Begins from first presentation by the potential donor to the transplant program..." First presentation is not clearly defined and we are concerned this could create an unintended burden on a potential living donor, who prior to the evaluation phase, may just beginning to collect information on living organ donation and not ready to meet with an advocate. In addition, it could cause a delay in evaluations of willing living organ donors as well put a constraint on their schedules to take even more time away from their jobs and personal responsibilities. Assigning every potential living donor candidate an advocate and requiring an interview even before they have undergone any conversation with the transplant program is overly burdensome for both the potential donor and the IDLA who may experience a significant increase in the number of interviews that need to occur. This new guidance also does not align with the policies of the Health Resources and Services Administration Organ Procurement and Transplant Network. Those standards allow flexibility on the timing for the requirements for an ILDA to be completed before organ procurement.¹ We believe that every living organ donor should be assigned an ILDA and be required to meet with that ILDA prior to consent of donating. However, timing of when that meeting should occur should be left to the organ donor and the transplant program in accordance with the OPTN standards and requirements for ILDA. For a potential donor to understand the role and responsibilities of the ILDA and the role and responsibilities of the ILDA they need to present to a transplant program. If a potential donor decides to withdraw from evaluation at any time, they or the ILDA on their behalf can do so without disclosing the reason for withdrawal to the recipient. As currently written, the National Kidney Foundation is concerned that the new interpretive guidance process creates more barriers for living organ donors and will create a delay in evaluating candidates for living organ donation.

Tag X 122 §482.98(d)(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis

The National Kidney Foundation strongly supports the need and role for an ILDA. We agree that an ILDA should be independent from the recipient's team. However, we find it impractical that the ILDA should not have any association with the transplant program and are concerned that the requirement creates a scenario where it is difficult to provide ILDAs who are knowledgeable

¹ Organ Procurement and Transplant Network Policies, effective July 11, 2019; accessed July 19, 2019
https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.

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and can appropriately assist the donor and respond to questions that may be best handled by individuals with an experience in solid organ transplantation. The 2008 interpretive guidance recognized this stating, “[B]y ‘independent we mean that the ‘individual(s)’ should function independently from the transplant team to avoid conflicts of interest. It does not mean that the individual must be employed by or supervised by someone outside of the hospital or outside the transplant program.’ The National Kidney Foundation believes the 2008 interpretive guidance was more appropriate than the new guidance and recommends that CMS return to this guidance. The 2008 guidance is also more closely aligned with Section 14.2 of the OPTN policies on the role of an ILDA.²

Sincerely,

Kevin Longino

Kevin Longino
CEO and transplant patient

Holly Mattix Kramer

Holly Mattix Kramer, MD, MPH
President

² Ibid.