



National
Kidney
Foundation®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

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

September 30, 2019

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

Dear Administrator Verma,

The National Kidney Foundation (NKF) is grateful for CMS' attention to our concerns regarding recent changes to the interpretive guidance for transplant centers that were finalized on May 24, 2019. In prior comments we submitted highlighting this issue, we described our concerns that the following revisions create barriers for willing organ donors and are at odds with the goals of the Advancing American Kidney Health Initiative:

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

We continue to believe that both revisions create concerning and unnecessary new burdens for potential living donors, transplant centers, and Independent Living Donor Advocates (ILDAs) and Independent Living Donor Advocate Teams (ILDATs). The revisions are especially concerning because they create new barriers to willing living organ donation in the absence of any clear rationale that supports the need to more tightly regulate how potential living donors interact with transplant centers. NKF continues to assert that CMS must revert to the 2008 interpretive guidance in order to avoid disincentivizing living organ donation.

NKF shares CMS' goal to protect the rights, wishes, and concerns of living donors. We understand CMS' has a role as a regulator to ensure that potential living donors understand what will happen during the evaluation and are not coerced to donate by involving an ILDA/T early in the donation process. We believe that the 2008 interpretive guidance is more than adequate to meet these aims. The revised interpretive guidance, rather than assuring the welfare of potential living donors, in fact exacerbates the complexities of an evaluation process that potential donors already view as arduous without providing potential living donors with any meaningful, additional benefit.

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Research conducted during the period when the 2008 interpretive guidelines were in effect demonstrates that living donors experience little to no coercion during the donation process. One study of 400 potential live donors had a mean pressure score of 1.1 (scale of 1-5 with 1 being no pressure) and nearly 80 percent scored a "1" indicating that experienced no pressure.¹

In addition, the revisions requiring an ILDA interview at "first presentation," increases the complexity of potential living donors' initial interactions with the transplant center and the length of the evaluation process, a key factor that causes potential living donors to drop out of the donation process and/or to report that it is burdensome. It is important to keep in mind that a long evaluation process may be infeasible for many potential living donors with jobs and other responsibilities that preclude several trips to a transplant center. Adding any additional time and the complexity to the evaluation process can be the difference between a potential living donor freely choosing to move forward in the donation or abandoning the process.

We further note that involving the ILDA/T at the time of "first presentation" to the transplant center does not add any additional value to the potential living donor. Only about 50 percent of potential living donors will progress in the donation process beyond their initial interactions with a transplant center and a preliminary medical screen.² As a preliminary step, potential living donors are interested in education about the donation process. As most people who are ruled out as potential donors are ruled out due to medical reasons, initial education and related screening about donation is best provided by a nurse or other professional with an understanding of solid organ transplantation. Having an ILDA provide this education as a result of the requirement that they are immediately available to the potential living donor does not honor the potential donor's time and responsibilities, protect the interests of potential living donors and, as we note above, would likely lengthen the evaluation process. The downstream effect of the new requirement will be to be a poor use of the interested donor's time, if they are going to be ruled out for medical reasons, as well as the ILDA/T's time.

With regard to the new requirements regarding who may serve as the ILDA or ILDA team, identifying a person/people who have no routine contact with the transplant team and yet who are well versed in the nuances of living kidney donation will not work for every transplant center. Transplant centers hold the privacy and primacy of the donor's needs paramount. In many centers the person(s) who would best serve as an advocate will be someone who does not work with the recipient's transplant team, but who is still affiliated with the transplant staff. The new requirement that the ILDA/T have no routine involvement with transplant activities is impractical and may have the unintended consequences of limiting the quality and quantity of support that the donor receives.

¹ King, E., Kahn, J., Erby, L., & Segev, D (2015 May). A Novel Tool to Evaluate Coercion, Pressure, and Motivation in Potential Live Kidney Donors. Poster session presented at the 2015 American Transplant Congress.

² Perlis, N., Connelly, M., D'A Honey, J. R., Pace, K. T., & Stewart, R. (2013). Evaluating potential live-renal donors: Causes for rejection, deferral and planned procedure type, a single-centre experience. *Canadian Urological Association Journal*, 2(1-2), 41-45. doi: 10.5489/cuaj.216

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Given the Administration's recently announced Advancing American Kidney Health Initiative and its bold goal of doubling the number of kidneys available for transplant in the next decade, NKF strongly advises against moving forward with the revised guidance, which runs counter to the Administration's efforts to increase the number of living donors by removing disincentives to donation."³

NKF Recommendations

NKF reiterates our support for returning to the 2008 interpretive guidance. We are extremely concerned that the revised interpretive guidance will disincentivize potential living donors from proceeding with donation and will create additional workflow and staffing issues for transplant centers. Our strong preference is that CMS decline to move forward with the revised interpretive guidance.

We appreciate CCSQ's proposed revisions to the interpretive guidance and offer the following comments. While not ideal, if revised as we recommend below, the amended interpretive guidance would be preferable to moving forward with the interpretive guidance finalized in May and may represent a balance between CMS' regulatory role and the needs and desires of willing organ donors, their families and caregivers, and the transplant community:

- NKF could support the revised language indicating every potential living donor be assigned and interviewed by an ILDA/T "prior to the evaluation and continuing to and through the discharge phase." We believe an initial screening process allowing for preliminary education about the donation process and review of the medical history prior to ILDA/T involvement is, at minimum, necessary to mitigate the burdens created by the interpretive guidance on potential living donors and transplant centers.
- NKF is concerned that the language regarding the restriction on involvement of the ILDA/T in transplant activities on a routine basis remains overly restrictive. We acknowledge that CCSQ has defined "routine" to mean that the ILDA/T is not involved in transplantation related activities and maintains separation with the transplant recipient and the recipient's transplant team. While we appreciate this clarification, we recommend revisions to the guideline language to reflect that there is more latitude for a member of the transplant team to serve as the ILDA/T while honoring the importance of the ILDA/T not being involved in recipient care in any way.

We are grateful for the opportunity to work with CMS to honor the gift that living kidney donors provide to the transplant recipient, their family, friends and caregivers, and the larger community. Please contact Kerry Willis, Chief Scientific Officer, at kerryw@kidney.org and Miriam Godwin, Health Policy Analyst, at miriam.godwin@kidney.org for further details on the position outlined in this letter.

³ The Office of the Assistant Secretary for Planning and Evaluation; US Department of Health and Human Services. (2019). *Advancing American Kidney Health*. *Advancing American Kidney Health*. Retrieved from <https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health>

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Sincerely,

Kevin Longino

Kevin Longino
CEO and transplant patient

Holly Mattix Kramer

Holly Mattix Kramer, MD, MPH
President