On behalf of the American Society of Transplantation (AST), representing a majority of medical professionals engaged in the field of solid organ transplantation, we applaud your leadership and continuous efforts to improve the nation’s healthcare delivery system. However, we are writing to share grave concerns regarding the new interpretive guidelines as it relates to the Independent Living Donor Advocate or Advocate Team (ILDA or ILDAT), specifically TAG X121 and TAG X122. We recognize and value the vital role played by the ILDA during the evaluation and selection of living organ donors. However, the new interpretation of the existing Conditions of Participation for transplant centers introduces a heavy burden on transplant centers that is unnecessary and is unlikely to enhance the safety of living donation or meaningfully improve patient care. Importantly, the requirement may introduce barriers, confusion and inefficiencies for donor candidates that negatively impact their experience and have the potential to deter living donation.

**TAG X121 Regulation §482.98(d) Standard: Independent Living Donor Advocate or Living Donor Advocate Team.**

The new guidelines state that “Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.

The great majority of potential living donor candidates that approach a transplant center do not complete the living donor evaluation process, usually because they are deemed ineligible by the transplant center to be living donors or because they chose to withdraw or delay the completion of their evaluation. Introducing the ILDA at the earliest step prior to a basic screening will substantially increase the workload of the ILDA and since the donor has not received even the most basic education regarding living donation, the ILDA will not be able to advocate for the living donor in any meaningful way. Importantly, as defined in OPTN/UNOS Policy, the role of the ILDA is to serve as an advocate to protect the interests of the donor candidate, not to serve as primary educator. Rather, it is living donor coordinator, social worker, physician and other clinical staff who educate, consent and coordinate the evaluation process. The ILDA reviews whether the living donor has received information on each area of the donation process, assists the donor in obtaining additional information from other professionals as needed, and advocates for the rights of potential donor. Importantly, conducting the ILDA interview prior to education from the clinical team may be confusing to many donor candidates, because there would be no substantive education yet to review. Coordinating an ILDA interview prior to prescreening would also reduce efficiency of the evaluation and pose burden to patients – inefficiencies in the
evaluation are documented as a substantial concern among donor candidates, who often must take unpaid time from work and other life responsibilities during the evaluation process. Since 1000s of potential donors make an initial enquiry or start the evaluation process without completing it, this also means that many ILDA interactions at this early stage would be unproductive and futile for both the potential donor and staff. This will likely make it more difficult for capable, empathetic and knowledgeable people to consider an ILDA role, as their primary duty would not be to support candidates with a high likelihood of approval in making an informed donation decision. Rather, the ILDA becomes part of the transplant center’s screening process at the earliest step, at a time point that is not logical or likely to be valuable to potential donors.

TAG X122; Regulation §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 new guideline states that “because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT must not be associated with the transplant program in any capacity even on a temporary or intermittent basis”.

We agree that it is critical that the ILDA’s purpose is to advocate for the donor candidate, and as such they should function independently from the transplant candidate’s team. However, we believe the new interpretation of independence is overly prescriptive. To appropriately serve the role as an advocate, the ILDA should be knowledgeable about donation and transplantation, which requires exposure to transplant activities and appropriate training and supervision. However, the ILDA is likely to be less knowledgeable than clinical staff about the consequences of living donation to assist the donor candidate in weighing his/her own specific likelihood of future morbidity based on current risk factors including donation surgery. Consequently, keeping the ILDA at arm’s length from the transplant center may result in a less effective donor advocate.

The ILDA must also have mechanisms to stop the evaluation process or the donation if there are concerns about the candidate’s rights or best interests, which may be compromised if they are disassociated from the program. Transplant Programs have developed different ways of ensuring both the independence and quality of the IDLA role, tailored for volume, staffing and workflows. The best way to ensure that these goals are met are by reviewing the job description for the ILDA, interviewing the ILDA, and reviewing the ILDA documentation, but not by prescribing that the ILDA be removed from the operations of the program.

We believe the public comment and burden review process exists to ensure regulations are vetted by those people who are affected by them, which in turn assures they are well-crafted to best protect patients and direct limited healthcare resources where they will do the most good. While we are sure these new IGs are well-intended, in many places they run counter to the interests of patients. We urge CMS to roll back the changes listed below to ones consistent with the final rule and current best practice. If CMS believes any of the regulations need to be changed, we would be eager to collaborate with you to propose evidence-based rule changes that make sense for patients and that will be received favorably through a public comment and burden analysis process.

We would be happy to provide further feedback or clarification on our specific comments in writing or at a mutually convenient call or meeting. Thank you for your attention to this, and your partnership in achieving the right regulations for our field.