

Statement on Living Donor and Transplant Candidate Selection Criteria

The American Society of Transplantation (AST) supports the many initiatives that have been undertaken to promote equitable access to transplantation in United States. We also support the existing regulations designed to ensure transplant programs practice fair and nondiscriminatory selection of candidates for transplant and living donation including the Americans with Disabilities and Rehabilitation Act, which prohibits eligibility criteria that tend to screen out persons with disabilities. Transplant surgeons, physicians, and their multidisciplinary teams approach all referrals of patients for transplant or living donation understanding the gravity of the selection process. Transplant programs engage in risk classification that prioritizes the greatest benefit in terms of longevity and quality of life. A decision to decline a candidate is made based on the risks to the patient outweighing the benefit a transplant (or donation) may provide. This decision is particularly complex and highly individualized. While there are clear uniform contraindications, such as transplantation in the setting of active metastatic cancer, more often there are a compendium of comorbidities related to medical, psychosocial, and psychological factors that collectively determine the risk of transplant or donation to outweigh the benefit from organ transplantation.

Mandatory standards are in place to require candidates to be evaluated by a multidisciplinary team who participate in selection committees where these decisions are made jointly. Programs are required to have written patient selection criteria, to provide these criteria to patients upon request, and to reference their written criteria when documenting selection committee decisions (variances are allowable, but must be documented). Transplant programs must notify patients within 10 business days of the selection committee's decision, and they must provide a phone number to patients for the Organ Procurement and Transplant Network (OPTN) should they have concerns¹.

These regulations are located in the <u>Centers for Medicare and Medicaid Services (CMS) Conditions of Participation</u>² for organ transplant programs, effective on June 28, 2007. Medicare approved programs in the United States must adhere to all conditions and standards. Compliance is evaluated and enforced through regular unannounced audits. Failure to adhere to the CMS conditions and standards results in citations up to including loss of certification. Among the many quality and operational requirements, CMS sets forth requirements to ensure fair and nondiscriminatory practices related to waitlisting and the distribution of organs and that selection criteria are written and provided to patients upon request.

Our Position:

The AST advocates for policies and practices that provide equitable access to transplant healthcare for vulnerable populations and upholds the cadre of regulations in place related to the patient selection process. We assert that transplant programs comply with the requirements for fair and nondiscriminatory practices. Transplant practitioners must retain the right to make the individualized determinations of which transplant and living donor patients are candidates for their programs based on the individual patient's comprehensive needs, and the available experience and resources at their

¹ OPTN Policy 3.5 (Patient Notification) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

² CMS Condition of Participation for Transplant Centers, Title 42, Chapter IV, Subchapter G, CFR §482.90 Patient and Living Donor Section and Section §482.94 Patient and Living Donor Management

transplant program. The AST fully supports transparency in the patient-provider relationship to ensure that patients are made aware of their healthcare options, including referral to other transplant programs. However, we are opposed to any measure that regulates individualized care decisions that may infringe on the ability to provide the optimal care that is at the very heart of practicing life-saving transplant medicine.

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