If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) **Standard: Patient selection.** Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Prior to placement on the center’s waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant center places a transplant candidate on its waiting list, the candidate’s medical record must contain documentation that the candidate’s blood type has been determined.

(3) When a patient is placed on a center’s waiting list or is selected to receive a transplant, the center must document in the patient’s medical record the patient selection criteria used.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

(b) **Standard: Living donor selection.** The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation.

(2) Document in the living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under §482.102.

§482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of donation.

(a) **Standard: Patient and living donor care.** The transplant center’s patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) **Standard: Waiting list management.** Transplant centers must keep their
waiting lists up to date on an ongoing basis, including:

1. Updating of waiting list patients’ clinical information;
2. Removing patients from the center’s waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center’s waiting list; and
3. Notifying the OPTN no later than 24 hours after a patient’s removal from the center’s waiting list.

(c) Standard: Patient records. Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center’s waiting list and who is admitted for organ transplantation.

1. For each patient who receives an evaluation for placement on a center’s waiting list, the center must document in the patient’s record that the patient (and in the case of a kidney patient, the patient’s usual dialysis facility) has been informed of his or her transplant status, including notification of:
   i. The patient’s placement on the center’s waiting list;
   ii. The center’s decision not to place the patient on its waiting list; or
   iii. The center’s inability to make a determination regarding the patient’s placement on its waiting list because further clinical testing or documentation is needed.

2. If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient’s record that the patient (and in the case of a kidney patient, the patient’s usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

3. In the case of patients admitted for organ transplants, transplant centers must maintain written records of:
   i. Multidisciplinary patient care planning during the transplant period; and
   ii. Multidisciplinary discharge planning for post-transplant care.

(d) Standard: Social services. The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

1. Completed a course of study with specialization in clinical practice and holds a master’s degree from a graduate school of social work accredited by the Council on Social Work Education; or
2. Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

(e) Standard: Nutritional services. Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) Standard: Components of a QAPI program. The transplant center’s QAPI program must use objective measures to evaluate the center’s performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center