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(1) CMS will compare each transplant program's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) program-specific report.

(2) CMS will not consider a program's patient and graft survival rates to be acceptable if:

(i) A program's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) *Exceptions.* (1) A heart-lung transplant program is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the program.

(2) An intestine transplant program is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the program.

(3) A pancreas transplant program is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the program.

(4) A program that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant program.

(5) A kidney transplant program that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014; 81 FR 79880, Nov. 14, 2016; 84 FR 51822, Sept. 30, 2019]

TRANSPLANT PROGRAM PROCESS REQUIREMENTS

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant program must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a program performs living donor transplants, the program 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 program's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant program 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 program'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 program 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 programs 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.

[72 FR 15273, Mar. 30, 2007, as amended at 84 FR 51822, Sept. 30, 2019]

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant programs must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant program is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ receipt*. After an organ arrives at a transplant program, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient.

(b) *Standard: Living donor transplantation*. If a program performs living donor transplants, the transplanting surgeon and another licensed health care professional at the program must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

[51 FR 22042, June 17, 1986, as amended at 77 FR 29076, May 16, 2012; 84 FR 51822, Sept. 30, 2019]

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

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

(a) *Standard: Patient and living donor care*. The transplant program'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 program 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 programs 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 program'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 program's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the program's waiting list.

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

(1) For each patient who receives an evaluation for placement on a program's waiting list, the program 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 program's waiting list;

(ii) The program's decision not to place the patient on its waiting list; or

(iii) The program'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 program must