

loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.

(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

(d) Instead of meeting all conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub. L. 100–203), as follows:

(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

**§ 482.78 Condition of participation: Emergency preparedness for transplant programs.**

A transplant program must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant program is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) *Standard: Policies and procedures.* A transplant program must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hos-

pital's emergency preparedness program.

(b) *Standard: Protocols with hospital and OPO.* A transplant program must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

[81 FR 64030, Sept. 16, 2016, as amended at 84 FR 51822, Sept. 30, 2019]

**TRANSPLANT CENTER DATA SUBMISSION, CLINICAL EXPERIENCE, AND OUTCOME REQUIREMENTS**

**§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant programs.**

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant programs must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant program must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a program, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a program requests Medicare approval to perform both adult and pediatric transplants.

## § 482.90

(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 multi-visceral 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.

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(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,