

§ 482.72

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

[51 FR 22042, June 17, 1986, as amended at 84 FR 51821, Sept. 30, 2019]

GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

§ 482.72 Condition of participation: OPTN membership.

A transplant program must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary pursuant to §121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

[51 FR 22042, June 17, 1986, as amended at 84 FR 51822, Sept. 30, 2019]

§ 482.74 Condition of participation: No- tification to CMS.

(a) A transplant program must notify CMS immediately of any significant changes related to the hospital’s transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant program designated to the OPTN as the program’s “primary transplant surgeon” or “primary transplant physician;”

(2) Termination of an agreement between the hospital in which the transplant program is located and an OPO

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for the recovery and receipt of organs as required by section 482.100; and

(3) Inactivation of the transplant program.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant program as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

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

§ 482.76 Condition of participation: Pe- diatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at §488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center’s approval to perform pediatric transplants.

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

(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in

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.