

§ 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

42 CFR Ch. IV (10–1–23 Edition)

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