

42 C.F.R. § 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.

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